EPA Registration No. 2724-427
Vol. 1

	s. Reily
PM 90: Janet And	CODING FORM
REGISTRANT/COMPANY NAME: Nell Mark International EPA REG./FILE SYMBOL 2724 + 127 ACTION CODE 350	Fast Track: Yes No Didney Reviewer Fact Wack Team Assigned by USH [Note: If Fast Track, you may need to change Reviewer's Name in PRAT.]
(New A.I/EUP'S/Tolerances: Yes No) DATE OF APPLICATION 1 03 0 EPA RECEIVED DATE 11 29 0 BPPD RECEIVED DATE 11 29 0 SUBMISSION BARCODE 9607655 ASSIGNED IN PRAT: Yes No COMPLETED BY 1 10 10 10 10 COMPLETED BY 1 10 10 10 COMPLETED BY 1 COMPLETED BY 1 10 COMPLETED BY 1 10 COMPLETED BY 1 COMPLETED BY 1 10 COMPLETED BY 1 10 COMPLETED BY 1 COMPLETED BY 1 10 COMPLETED BY 1 COMPLETED BY 1 10 COMPLETED BY 1 10 COMPLETED BY 1 COMPLETED BY 1	Notification alt. brand rame
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FINAL ACTION RESPONSE CODE: 1-11-02	સું સું સુ સુ સુ સુ સુ સુસુસુસુ સુ સુ સુ સુ સુ
MOS:(1) Cite All	turing Use: Yes No 🗆

Note:
Daracon D-30 exist for 10807-6

aper exist for 1839-86+ 6836-89

3724-427

NOTIFICATION REVIEW COORDINATOR- CHECK LIST

1) BPPD Coding Form attached? YES INO
(No- get one from front desk or create bean with PRATS. using Action code 332)
2) The following conditions must be met:
a) 8570-1 form complete
including the certification statement verbatim from PR Notice 98-10.
including the certification statement verbatini from the two too.
b) ALL Changes to label are identified.
Registrant should have described all changes to the label on 8570-1 form or letter, and
preferably highlighted changes on label.
1
c) The changes make sense.
If you have questions check with RAL, Susanne, Jim, Willie or Branch Chief.
d) Advisory statements are not modified
d) Advisory statements are not modified.
Advisory statements can not be made by notification
e) ALL of the requested changes to the label are covered by PR Notice 98-10
-The table on the end of 98-10 is helpful for finding pertinent sections
4
f) The labeling changes conform with latest approved Label Review Manual.
00.10
If any of the above conditions for item 2 are not met.: 98-10, 51. A.
If any of the above conditions for item 2 are not met.:
a. Inform RAL of problem.
b. Provide RAL Rejection form letter.
c. Log action out of PRATS.
b. Provide RAL Rejection form letter. c. Log action out of PRATS.
If all of the above conditions for item 2 are met, continue

3) If a product name change was submitted: .

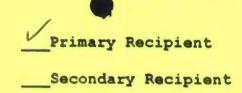
- a) Check REFS to make sure name not taken
- b) Make sure- new name does not present questionable claims (Eg. "Natural Golden Oil",
- or "No More Rats".)- Consult Label Review Manual. (Chap. 12) See RAL if not sure.
- 4) If use sites are being deleted
- -Contact Jim Hollins of ISB/IRSD. Use site deletions may require Federal Register notice before label can be approved.

5) If label notification is acceptable:

- a) STAMP submitted label and 8570-1 form with "NOTIFICATION dated____", insert date and your initials.
- b) File notification material in file jacket.
- c) Log action out of PRATS. If no response required, enter "37" as PRAT response code
- d) Transfer jacket to SIG for coding, with attached note indicating type of notification

PD Label Amendment Check I Application Date: _9-19-EPA File Symbol/Reg. No.: 2724 Jim DOWNING Check List current as of 4-5-200 No. Check List Item Yes No 1. Application Form (EPA Form 8570-1) -signed & complete including package type If NO, STOP! Call applicant and have them correct application and resubmit. Fast-Track? 1a. 2. Amendment covered by PR Notice 98-10 (Notifications)? If YES, STOP. Call applicant and inform them that this submission will be converted to a notification. After closing out in PRATS, forward to Notification Review Coordinator. 3. Final printed labeling received for previous action? If NO. Stop! E-mail applicant and request final printed labeling (FPL). Let them know that nothing will happen regarding this action until FPL is submitted. File copy of e-mail message as record of notification. Log out of PRATS (label deficiency). 4. Data and Data Matrix (EPA Form 8570-35) a) using Selective Method? [If NO, (Data Matrix not required), skip to Item 5.] 1) Complete Data Matrix. Minimum Data Matrix for registration includes: Product specific acute tox and product chemistry data, plus Efficacy data for Public Health pests claimed on label. * label now claims non-biting midges (not a Public Health sest) b) Adequate Product Specific data c) Registered source used for active ingredient? If Yes, active ingredient is from a registered source and generic data should be satisfied by registered source. Skip to Item 5. If No, generic data is necessary. d) Data passed 86-5? (Data formatting PR Notice) e) Public copy of Matrix provided? (As required by PRN 98-5) 5. Certification with Respect to Citation of Data (EPA Form 8570-34) See 40 CFR 152.80-98 and PR Notice 98-5 [Note: If no data are required or submitted, a Certification with Respect to Citation of Data form is not needed. This is often true for minor amendments.] a) Did applicant check a Method of Support? b) General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method? c) Is the form signed and dated? d) Check form and Data Matrix; are Exclusive Use data cited from other sources? 1.) If Yes, is the required authorization letter included in application? 6. NA Label(s) Review Date of Label Review: Label(s) agrees with current Label Review Manual and appropriate REDS a. b. Labeling from acute tox, product chemistry, and efficacy data (Public Health pests) Nominal concentration of active ingredient shown in ingredients statement C. d. Viability included as substatement of Ingredient Statement (if live microbial, e.i., cfu/gram) Storage and disposal instructions agree with container types listed on application form e. f. Unique Product Name for Same Company (Check REFS) g. Labeling is acceptable. Corrections or changes are NOT necessary.

Bap-847-330-5315



MRID 45113701

NOTICE OF RECEIPT OF 6(a) (2) SUBMISSION

DATE: 5-8-2000

FROM: Information Services Branch

Information Resources and Services Division

TO: SHERYL REILLY

The 6(a)(2) Team has taken steps to get this screened by the appropriate science staff.

Screening determines the priority and timeframe for review.

As soon as screen results are received by ISB, you will be informed by your division 6(a)(2) Team representative. This information will determine instructions for review.

Please do not put this study or letter into review until you receive screen results and review instructions from your division 6(a)(2) Team representative.

If you have any questions, please contact Kathleen O'Malley. She is located in Room 224 CM2 and can be reached on 305-5411.

Primary Recipient

Secondary Recipient

MRID 45113701

NOTICE OF RECEIPT OF 6(a) (2) SUBMISSION

DATE: 5-8- 2000

FROM: Information Services Branch

Information Resources and Services Division

TO: PM - ADAM HEYWARD CRM - MICHAEL NIEUES

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Please do not put this study or letter into review until you receive screen results and review instructions from your division 6(a)(2) Team representative.

If you have any questions, please contact Kathleen O'Malley. She is located in Room 224 CM2 and can be reached on 305-5411.

MAY 5 2000

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

WELLMARK INTERNATIONAL 1000 TOWER LANE SUITE 245 BENSENVILLE, IL 60106

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 05/03/00. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

451137-00

Wellmark

May 3, 2000

Ms. Kate Bouvé FIFRA 6(a)(2) Office of Pesticide Programs (H7504C) U.S. Environmental Protection Agency 1921 Jefferson Davis Hwy. Arlington, VA 22202

Subject:

FIFRA 6(a)(2) REPORTING (STUDY SUBMISSION)

FOR ZOËCON RF-342 EMULSIFIABLE CONCENTRATE

EPA REG. NO. 2724-427

Dear Ms. Bouvé:

Wellmark International is submitting a primary eye irritation study in rabbits under provision of FIFRA Section 6(a)(2) for EPA Reg. No. 2724-427. Three copies of the study are enclosed along with a Transmittal Document.

In the primary eye irritation study in rabbits #SLS 3122.8, one of six rabbits in the non-wash, treated group exhibited corneal involvement up to day 21 post-dosing. The remaining five of six rabbits in the non-wash, treated group had eye irritation that cleared by day 10. In the washed, treated group, all animals had minimal eye irritation at 72 hours and no irritation at day 4. Although the study results indicate that this formulation would be a severe eye irritant (tox cat. I), it is important to note that Wellmark has yet to receive an adverse incident report for this current formulation. Additionally, this product is marketed to a specialized niche group that has many years of experience with this product's application.

This study was conducted in anticipation of methoprene end-use product reregistration data requirements. However, ultimately the study was not required for reregistration and inadvertently it was not submitted. This fact was recently discovered when reviewing the product data base in relation to a formulation amendment required for reasons unrelated to eye irritation. Wellmark will be submitting this formulation amendment with an ocular irritation study in the third quarter 2000.

Please contact me at (630) 227-6017 should you have any questions regarding this submission.

Sincerely,

Nancy Huebi

Regulatory Label Specialist

Enclosures:

SLS Study No. 3122.8 (Eye)

CC:

S. Spaulding/C. Elmi/D. Crawford

TRANSMITTAL DOCUMENT

SUBMITTED BY

Wellmark International 1000 Tower Lane Bensenville, Illinois 60160

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Submission of Primary Eye Irritation study for Dianex RF-342 EC in Compliance with FIFRA 6(a)(2) Reporting Requirements

TRANSMITTAL DATE

May 3, 2000

LIST OF SUBMITTED STUDIES

Volume 1 of 1 Primary Eye Irritation Study of Dianex RF-342 in Rabbits, Springborn Life Sciences, Inc. study # 3122.8, 2/13/89.

MRID # _______

COMPANY OFFICIAL:

Nancy Huebl

Registration Specialist

COMPANY NAME:

Wellmark International

COMPANY CONTACT:

Nancy Huebl (630) 227-6017

Cancy Guebl

	100	
V	Primary R	ecipient
	Secondary	Recipient

NOTICE OF RECEIPT OF 6(a) (2) SUBMISSION

DATE: 9/28/00

FROM: Information Services Branch

Information Resources and Services Division

o: Sheyl Reilly, BPPD

The 6(a)(2) Team has taken steps to get this screened by the appropriate science staff.

Screening determines the priority and timeframe for review.

As soon as screen results are received by ISB, you will be informed by your division 6(a)(2) Team representative. This information will determine instructions for review.

Please do not put this study or letter into review until you receive screen results and review instructions from your division 6(a)(2) Team representative.

If you have any questions, please contact Kathleen O'Malley. She is located in Room 224 CM2 and can be reached on 305-5411.

Kathleer O'Mally 3-5411

methoprene 6(a) studies

primary eye irritation

Zoecon EC

2724-427

MDID MRID 45113701 status? review label changes-30 days 10/13 Called Kathleen to inform her about this amendment - formulation change due to the submitted 6(e)(2) data (see above).

DP BARCODE: D272819

CASE: 004629

DATA PACKAGE RECORD

SUBMISSION: S580294

BEAN SHEET

DATE: 02/20/01

Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION

ACTION: 405 6(A)(2) ADVERSE DATA

CHEMICALS: 105401 Methoprene (ANSI)

32.8000%

ID#: ,002724-00427 ZOECON RF-342 EMULSIFIABLE CONCENTRATE Label a mend in ent.

COMPANY: 002724 WELLMARK INTERNATIONAL

PRODUCT MANAGER: 90 JANET ANDERSEN

703-308-8128 ROOM: CS1

ROOM: CS1 5TH FL

PM TEAM REVIEWER: JIM DOWNING 703-308-9071 ROOM: CS1

RECEIVED DATE: 05/16/00 DUE OUT DATE: 07/25/00

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 272819 EXPEDITE: N DATE SENT: 02/20/01 DATE RET.: / /

CHEMICAL: 105401 Methoprene (ANSI)

DP TYPE: 001

CSF: Y LABEL: Y

ASSIGNED TO DATE IN DATE OUT ADMIN DUE DATE: 05/31/01
DIV: BPPD / / NEGOT DATE: 05/31/01
BRAN: BPPD-IO / / PROJ DATE: / /
SECT: IO / / /

* * * DATA REVIEW INSTRUCTIONS * * *

Freshteh: This amendment is to change the formula (remove an offending inert - eye irritation) and change the label, adding mushroom culture, stored product insects in cereal grains, grain sorghum, corn, birdseed and peanuts, plus use against flies and midges in Waste Water Treatment Facilities.

Product chemistry, acute tox data and efficacy data is submitted to support the amendment.

Please review the data to see that it supports the new formulation and amended label (new use sites).

Thanks, Jim

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

ZOECON RF-342 [Optional text] Concentrate

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth1

An Insect Growth Regulator for the Control of [Insect Pests in Tobacco Processing and Storage Facilities] [to Prevent the Emergence of Adult Sciarid Flies In Mushroom Culture] [Stored Product Insects in Cereal Grains, Grain Sorghum (Milo), Corn (except Sweet Corn and Popcons, Bildsood, Tiller Flies and Midges [to Prevent the Emergence of Adult Filter Flies and Midges] Sweet Corn and Popcorn), Birdseed, and Peanuts]

ACTIVE INGREDIENT:

OTHER INGREDIENTS*:66.4%

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements

proposed

EPA Reg. No. 2724-427

EPA Est. No.

NET CONTENTS:

^{*}Contains petroleum distillates

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

	FIRST AID
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or doctor for treatment advice.
lf on skin	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If swallowed	Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give ANY liquid to the person. Do not give anything by mouth to an unconscious person.
Have the prod	uct container or label with you when calling a poison control
center or docto	or, or going for treatment. You may also contact [phone
number] for en	nergency medical treatment information.
NOTE TO PH'	YSICIAN: Contains petroleum distillate – vomiting may cause
aspiration pne	umonia.

(Include WPS for APEX Mushroom Use pattern)

[Personal Protective Equipment (PPE):
Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber (≥ 14 mils), barrier laminate, or viten (> 14 mils). Follow manufactured instructions for closning and maintaining viton (≥ 14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.]

Engineering Controls Statements:

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

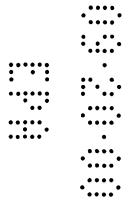
User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS: [This product is toxic to aquatic dipteran. Using it in a manner other than that described by the label could result in harm to non-target aquatic invertebrates]. Do not contaminate water when disposing of rinsate or equipment washwaters.

[Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.]



[AGRICULTURALUSE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

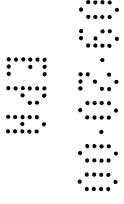
Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber (≥ 14 mils), barrier laminate, or viton (≥ 14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.]



(Directions for Use for RF-9811 EC [DIANEX]-Stored Tobacco Products) INTRODUCTION: RF-9811 EC is an emulsifiable formulation of the insect growth regulator, (S)-methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead, it interferes with the normal processes of insect development and prevents adult emergence. RF-9811 EC, when used according to label directions, controls the following insects:

Almond moth (Ephestia cautella)

Cigarette beetle (Lasioderma serricome)

Sawtooth grain beetle (Oryzaephilus surinamensis)

Red flour beetle (*Tribolium castaneum*)

Tobacco moth (Ephestia elutella)

Indian meal moth (Plodia interpunctella)

Lesser grain borer (Rhyzopertha dominica)

Merchant grain beetle (Oryzaephilus mercator)

Confused flour beetle (Tribolium confusum)

Warehouse beetle (Trogoderma spp.)

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply RF-9811 EC as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply RF-9811 EC at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of RF-9811 EC to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add RF-9811 EC, mix and complete filling with recommended quantity of water. Use បាប់ by spray solution within 24 hours of mixing. Agitate before each use.

(Directions for Use for DIACON -Stored Product Insects)

PRODUCT INFORMATION: (S)-methoprene, the active ingredient in DIACON[®], protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, DIACON is not an adulticide, but its residual activity prevents the development of larvae into adults. DIACON, when used according to the label directions, prevents regeneration of the following insects: almond moth, Indian meal moth, cigarette beetle, lesser grain borer, sawtooth grain beetle, merchant grain beetle, red flour beetle, and confused flour beetle. Existing insect populations should be treated before applying DIACON for residual protection.

If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain-damage from existing insects. Refer to FGIS regulations for stored grain for more information on sampling and insect thresholds.

Stored Grain: For protection of stored food, feed, oil and seed grains against stored grain insects - for optimum results, thoroughly clean and treat grain storage areas prior to storage of grain. DIACON may also be applied as a top-dressing to stored products that have already been placed into bins or storage areas. Use the rate of 2.5 - 5 ppm for this type of application. Avoid flooding of top-dress area.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED: Dilute DIACON with water or FDA-approved food grade oils* or soybean oil and apply to the moving grain stream as a coarse spray to give a deposit of 5 ppm of DIACON on the grain. Use a final water solution volume of 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. Final spray volumes of oil solutions should be applied at the oil manufacturer's rates. Agitation of water or oil solutions is necessary.

For maximum residual and efficacy, use the rate of 5 ppm. For shorter term residual, lower rates may apply, but do not use rates less than 1 ppm.

DIACON is to be applied in solution in accordance with the general directions to stored products at the following rates per 1000 bushels to provide treatment with 5 ppm concentrations of DIACON. When using lower rates, use the appropriate amount of formulation to achieve the desired application rate:

	<u>5 p</u>	pm	2.5	ppm	1 pr	<u>m</u>
	fl oz	<u>ml</u>	<u>fl oz</u>	<u>ml</u>	fl oz	<u>ml</u>
Wheat	7.70	228	4.0	114	1.54	46
Corn	7.10	212	3.5	106	1.42	43
Grain sorghum (Milo)	7.10	212	3.5	106	1.42	43
Barley	6.10	182	3.0	91	1.22	37
Rice	5.70	170	3.0	85	1.10	34
Oats	4.10	121	2.0	61	0.80	25
Peanuts*	3.85	115	2.0	60	0.80	24

^{*}For peanuts, use water solution only

USE PRECAUTIONS:

- Apply DIACON grain protectant only to grain of known treatment history, apply no more than once per crop.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of DIACON to a spray tank partially filled with water or mineral oil, mix and complete filling with recommended quantity of carrier.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.
- Avoid application at extremely dusty sites.

DIACON may also be used as a fogging concentrate or surface spray for the treatment of warehouses, silos, storage bins or other stored commodity areas. For application of DIACON as a fogging or space spray, use the following directions.

Application with Cold Aerosol Generators: Apply DIACON as a mist or aerosol. Dilute with water or oil as required following the instructions of the spray equipment manufacturer. Apply DIACON at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of DIACON to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add DIACON, mixeand complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

(Directions for Use for APEX – Mushrooms)
(S)-methoprene, the active ingredient in APEX® insect growth regulator (IGR) is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of (S)-methoprene does not result in immediate insect kill, it interferes with the normal process of insect development. APEX will prevent the emergence of adult sciarid flies when incorporated into the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adults present at the time of application will not be affected. If high adult populations are present initially, use of a conventional adulticide will ensure the best overall results. After treatment with APEX, larvae will continue to develop to the pupal stage where they will die. Estimation of adult fly populations should be no earlier than 2 weeks after treatment to assess the full benefit of APEX.

METHOD, RATE, AND TIMING OF APPLICATION: For best results, APEX should be incorporated in the mushroom growing medium.

Follow either **METHOD A**, **METHOD B**, **or METHOD C** Application Instructions.

A. INCORPORATE IN CASING AT TIME OF CASING

Apply APEX at the rate of 5½ fluid ounces per 1000 sq ft (fl oz/1000 sq ft). Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after placement.

B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

In Compost: Apply APEX at the rate of 5½ fl oz/1000 sq ft in adequate water for even distribution. Spray or sprinkle on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

In Casing: Apply APEX at the rate of 2½ fl oz/1000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a 16-day or longer spawn run, a split application can be used.

First Application, on compost: Apply APEX 12-13 days after spawning. Drench APEX evenly on the surface at the rate of 2¾ fl oz/1000 sq ft in adequate water for even distribution.

Second Application, in casing: Apply APEX at the rate of 2¾ fl oz/1000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after ••• setting it in place.

MIXING AND HANDLING INSTRUCTIONS

- 1. Add the measured amount of APEX to a spray tank partially filled with water, mix, and complete filling with recommended quantity of water.
- 2. Use diluted spray solution within 48 hours of mixing. Agitate before each use.

In most cases, treatment with APEX has a beneficial effect on mushroom yield through control of damaging sciarid fly larvae. Due to the widely differing practices followed in mushroom culture, the user should conduct test treatments on small plots to determine that reduced crop yields will not occur under his own cultural conditions.



Directions for Use for midges/filter flies

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

MIXING AND HANDLING INSTRUCTIONS:

Partially fill spray container with water; then add the recommended amount of RF-9811 EC, agitate, and complete filling. Agitate mildly during application. Agitation can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

RECOMMENDED APPLICATIONS

Waste Water Treatment Facility Pests: Use RF-9811 EC in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where midges, filter flies, and other nuisance aquatic insect pests are a problem.

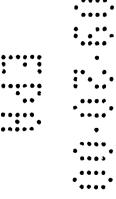
What to Expect in Waste Water Treatment Facilities Continuous Flow Sewage (waste water)

In order to achieve effective results, RF-9811 EC must be applied daily for at least 2 weeks. If applications are not made on a continuous basis, erratic results may occur. Following initial applications of RF-9811 EC, a gradual reduction in the number of adult pests will be seen over <u>approximately</u> a <u>1 week</u> period. Reduction in adult populations will be very noticeable within a 2 week period following continuous application. Due to varying conditions or heavy infestations, a longer period may be necessary for control. Since the mode of action of RF-9811 EC is to prevent adult emergence, existing adults and pupa present at the time of initial application will complete their life cycle.

As adult suppression peaks, use a maintenance rate of RF-9811 EC for continuous protection from population rebound. However, if application of RF-9811 EC is halted following population suppression, rebound of the population can be expected within 2 to 3 weeks after stopping application. For continuous suppression throughout the pest season, continue applications of RF-9811 EC

Sludge or Solid Waste Applications

For solid waste applications, use the initial high rate. The dilution should be applied until the drying beds have been filled. Following filling of the drying beds, halt the dilution application. Make applications of the dilution at the <u>influent</u> side as the sludge or solids enter into the drying beds. Application of RF-9811 EC to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.



METHODS OF APPLICATION

Waste Water Treatment Facilities: Dilute RF-9811 EC with water prior to use. Apply RF-9811 EC by using a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence appropriate product dilution. Depending on the dosage rate, prepare desired volume of dilution to apply over a 24 hour period (day tank), or in cases of sludge beds, applied until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of RF-9811 EC over a 24 hour period. Mix sufficient material in advance to provide for applications longer than 24 hours. Metering pumps that are capable of delivering material for more than 24 hours are highly recommended.

APPLICATION RATE

Waste Water Treatment Pests:

Initial Application - 2.5 to 3.0 ounces of RF-9811 EC per 1 million gallons of sewage (waste water) in sufficient water to apply uniformly at the influent side over a 24 hour period.

Maintenance Rate - 1.5 to 2.0 ounces RF-9811 EC per 1 million gallons of sewage waste water in sufficient water to apply uniformly at the influent side over a 24 hour period.

To achieve effective results, use initial application rates on a daily basis for 2 weeks, without interruption. Use sufficient water/RF-9811 EC to achieve uniform application to sewage (waste water) over a 24 hour period. Make application of the dilution at the <u>influent</u> side of the particular area to be treated.]

Maintain initial rate of application for 2 weeks and then for continued effectiveness, follow the directions for the maintenance rate.

APPLICATION SITES

Waste Water Treatment Facilities: Make applications of RF-9811 EC to sewage as it <u>flows into</u> trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem.

Make RF-9811 EC applications as the sewage enters (influent areas) the targeted processing area. Failure to add the material at the influent side may result in erratic results.

STORAGE and DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Storage - Store in a cool dry place. Pesticide Disposal - Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

WARRANTY AND CONDITIONS OF SALE

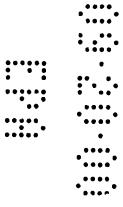
Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

APEX®, DIACON®, and DIANEX®, are registered trademarks of Wellmark International.

Wellmark International Schaumburg IL 60173

Made in USA

For information or in case of an emergency, call 1-800-XXX-XXXX. Visit our Web site: [web site address]



BPPD WORK ASSIGNMENT #69 ORNL IAG #DW 89938591-01

Date: 02-21-01 Date Mailed: 02-21-01

- 1. Oak Ridge National Laboratory (ORNL) shall independently review the studies identified below and prepare for each study a Data Evaluation Record (DER). In addition to its scientific expertise, the ORNL shall use the appropriate OPP Test Guidelines, science policy documents, and other guidelines and materials provided to ORNL for the purpose of training, orientation and guidance concerning the preparation of DERs under the IAG.
- 2. For technical/scientific questions that cannot be resolved by the ORNL without input from BPPD science staff, the ORNL shall contact: Freshteh Toghrol. MRIDs and Studies for this work assignment are respectfully as follows:

EPA Registration No. 002724-00427. Product Name: Zoecon RF-342 Emulsifiable Concentrate. Company: Wellmark International.

Table 1.

DP Barcode	MRID#	Study Type	Estimated Hours
D272819/002724-00427	452144-01	Physical/Chemical Properties	4
D272819/002724-00427	452144-02	Product Chemistry/Analytical Methods	4
D272819/002724-00427	452144-03	Product Chemistry/Manufacturing Process	4
D272819/002724-00427	452144-04	Acute Oral Toxicity	4
D272819/002724-00427	452144-05	Acute Dermal Toxicity	4
D272819/002724-00427	452144-06	Primary Skin Irritation	4
D272819/002724-00427	452144-07	Acute Eye Irritation	4
D272819/002724-00427	452144-08	Hypersensitivity in Guinea Pigs	4
D272819/002724-00427	452144-09	Acute Inhalation/Rats	4
D272819/002724-00427	452144-10	Efficacy Against Mushroom Sciarid Flies	6
D272819/002724-00427	452144-11	Efficacy to Control Beetles in Stored Wheat	6
D272819/002724-00427	452144-12	Effective Filter Fly Control	6
Total Estimated Cost			54

- 3. Transmittal dates for the First Draft of the DERs to BPPD shall conform generally to the "Working Days" specified in ORNL Proposal #1824-G018-A1. The Work Assignment Manager will review the proposed Transmittal and Due Dates and negotiate a mutually acceptable schedule for EPA and ORNL for delivering the first draft of the DERs. For research reports that do not include estimated hours, please notify the Work Assignment Manager with any questions or hour estimates.
- 4. The ORNL shall conduct its routing Quality Assurance/Quality Control reviews as specified in its QA/QC plan for the IAG.

Freshteh Toghrol

2/21/01

Date



(S)-METHOPRENE TECHNICAL

Registration number: 002724-00442

Please report any suspected data errors to <u>USEPA/OPP</u>. View USEPA/OPP Label Images (tiff format) for this Product: Click Here

Company: WELLMARK INTERNATIONAL

1100 EAST WOODFIELD ROAD, SUITE 500 SCHAUMBURG, IL 60173

USA

Contact: STEVE SPAULDING Contact Phone: 6302276074

Status: Active

Approval date: 05/10/1989 Cancel or Transfer date: // Existing Stocks date:: // Cancel reason:

EPA Product manager: Sheryl Reilly -- (703)308-8269

Chemical(s):

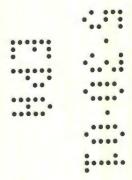
94.0000 % of (105402)

Chemical Names: (Common Name, Synonym, Trade Names)

o CAS REG. NO. 65733-16-6

DODECADIENOIC ACID, 11-METHOXY-3,7,11-TRIMETHYL-, 1-METHYLETHYL ESTER, (S-(E,E)) ISOPROPYL (2E,4E,7S)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE

• METHOPRENE



USEPA/OPP PC Code: 105402

Common Name:

METHOPRENE

CAS REG. NO. 65733-16-6

Synonym(s):

• DODECADIENOIC ACID, 11-METHOXY-3,7,11-TRIMETHYL-, 1-METHYLETHYL ESTER, (S-(E,E))-

Scientific Name(s):

• ISOPROPYL (2E,4E,7S)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE

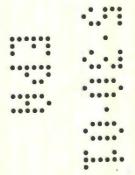
CAS Numbers

CAS REG. NO. 65733-16-6

0065733166

List all products for this chemical or, just the active products.

<u>List Unique Registrants (Active/Inactive)</u>



METHOPRENE TECHNICAL

Registration number: 002724-00441

Please report any suspected data errors to <u>USEPA/OPP</u>. View <u>USEPA/OPP</u> Label Images (tiff format) for this Product: <u>Click Here</u>

Company: WELLMARK INTERNATIONAL

1100 EAST WOODFIELD ROAD, SUITE 500

SCHAUMBURG, IL 60173

USA

Contact: STEVE SPAULDING Contact Phone: 6302276074

Status: Active

Approval date: 10/14/1988 Cancel or Transfer date: // Existing Stocks date:: //

Cancel reason:

EPA Product manager: Sheryl Reilly -- (703)308-8269

Chemical(s):

90.0000 % of (105401)

Chemical Names: (Common Name, Synonym, Trade Names)

- ALTOSID BRIQUETS
- ALTOSID CP10
- ALTOSID SR 10
- CAS REG. NO. 40596-69-8
- DODECADIENOIC ACID, 11-METHOXY-3,7,11-TRIMETHYL-, 1-METHYLETHYL ESTER, (E,E)-
- DODECADIENOIC ACID, 11-METHOXY-3,7,11-TRIMETHYL-, ISPROPYL ESTER, (E,E)-
- ENT-70460
- ISOPROPYL (2E,4E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE
- ISOPROPYL (E,E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE
- KABAT
- MANTA
- METHOPRENE (ANSI)
- METHYLETHYL (E,E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE
- ZR-515

ZOECON RF-342 EMULSIFIABLE CONCENTRATE

Registration number: 002724-00427

Please report any suspected data errors to <u>USEPA/OPP</u>. View <u>USEPA/OPP</u> Label Images (tiff format) for this Product: <u>Click Here</u>

Company: WELLMARK INTERNATIONAL

1100 EAST WOODFIELD ROAD, SUITE 500 SCHAUMBURG, IL 60173 USA Contact: STEVE SPAULDING

Contact: STEVE SPAULDING Contact Phone: 6302276074

Status: Active Approval date: 12/06/1989 Cancel or Transfer date: // Existing Stocks date:: // Cancel reason:

EPA Product manager: Sheryl Reilly -- (703)308-8269 Chemical(s):

32.8000 % of (105401)

Chemical Names:(Common Name, Synonym, Trade Names)

- ALTOSID BRIOUETS
- ALTOSID CP10
- ALTOSID SR 10

ZOECON RF-342 EMULSIFIABLE CONCENTRATE

Registration number: 002724-00427

Please report any suspected data errors to USEPA/OPP.

View USEPA/OPP Label Images (tiff format) for this Product: Click Here

Company: WELLMARK INTERNATIONAL

1100 EAST WOODFIELD ROAD, SUITE 500

SCHAUMBURG, IL 60173

USA

Contact: STEVE SPAULDING Contact Phone: 6302276074

Status: Active

Approval date: 12/06/1989 Cancel or Transfer date: // Existing Stocks date:: //

Cancel reason:

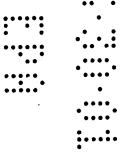
EPA Product manager: Sheryl Reilly -- (703)308-8269

Chemical(s):

32.8000 % of (105401)

Chemical Names: (Common Name, Synonym, Trade Names)

- ALTOSID BRIQUETS
- ALTOSID CP10
- ALTOSID SR 10
- o CAS REG. NO. 40596-69-8
- DODECADIENOIC ACID, 11-METHOXY-3,7,11-TRIMETHYL-, 1-METHYLETHYL ESTER, (E,E)-
- DODECADIENOIC ACID, 11-METHOXY-3,7,11-TRIMETHYL-, ISPROPYL ESTER, (E,E)-
- ENT-70460
- ISOPROPYL (2E,4E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE
- ISOPROPYL (E,É)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE
- KABAT
- MANTA
- METHOPRENE (ANSI)
- METHYLETHYL (E,E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE
- 。ZR-515



PC Code: 105401

Common Name:

- METHOPRENE (ANSI)
- CAS REG. NO. 40596-69-8

Synonym(s):

- METHYLETHYL (E,E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE
 DODECADIENOIC ACID, 11-METHOXY-3,7,11-TRIMETHYL-, 1-METHYLETHYL ESTER, (E,E)DODECADIENOIC ACID, 11-METHOXY-3,7,11-TRIMETHYL-, ISPROPYL ESTER, (E,E)ISOPROPYL (E,E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE

- Trade Name(s):

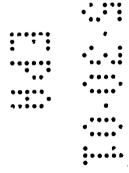
 ALTOSID BRIQUETS
 - o ZR-515
 - ENT-70460
 - ALTOSID SR 10
 - KABAT
 - MANTA
 - ALTOSID CP10

Scientific Name(s):

• ISOPROPÝL (2E,4E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE

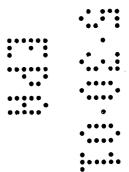
- o CAS REG. NO. 40596-69-8
- 0040596698

List all products for this chemical or, just the active products.



- o CAS REG. NO. 40596-69-8
- DODECADIENOIC ACID, 11-METHOXY-3,7,11-TRIMETHYL-, 1-METHYLETHYL ESTER, (E,E)DODECADIENOIC ACID, 11-METHOXY-3,7,11-TRIMETHYL-, ISPROPYL ESTER, (E,E)-

- ISOPROPYL (2E,4E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE ISOPROPYL (E,E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE
- KABAT
- MANTA
- METHOPRENE (ANSI)
- METHYLETHYL (E,E)-11-METHOXY-3,7,11-TRIMETHYL-2,4-DODECADIENOATE



PM 90: Janet Andersen

REGISTRANT/COMPANY NAME:	Fast Track: Yes□ No□
Well Mark	Reviewer Jan Douning Assigned by
EPA REG./FILE SYMBOL 2724-427 ACTION CODE 68	[Note: If Fast Track, you may need to change Reviewer's Name in PRAT.]
(New A.I/EUP'S/Tolerances: Yes Not) DATE OF APPLICATION 10801	Final Printed labels
EPA RECEIVED DATE 10 10 0	;3
PM RECEIVED DATE 10 11 01 SUBMISSION BARCODE 5530588	:
ASSIGNED IN PRAT: Yes No	
COMPLETED BY SW DATE 10 15/01	
LOGGED IN BRATS: Yes No DATE 10/6/01	.cp
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FINAL ACTION	
RESPONSE CODE:	
RESPONSE DATE:	
MOS:(1) Cite All(4) Not Applicable(8) Selective	
CRP Yes No No No No Manufacturing Use: Yes N	

BPPD PRAT ACTION CODING FORM

PM 90: Janet Andersen	(ASSIGNED BY: SK	ring .
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(NEW a.i./EUPs/Tolerances: Yes	/No)	
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PM RECEIVED DATE 5/3/	. 10.2	
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Restricted Use: Yes	No	
Manufacturing Use: Yes	No_ herd	
Exclusive Use: Yes	No	

JACKET CODING FORM

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Urand States Environmental Protection Agency File in Tacket

MAR 1 2 2004

Nancy Huebl Wellmark International 1100 East Woodfield Road, Suite 500 Schaumburg, IL 60173

Sub: RF-9811-EC

Your application dated July 21, 2003 to revise the directions for use and to add new uses (stored commodites) to the label as covered under the existing tolerance exemption

Dear Ms. Huebl:

The labeling amendment referred to above submitted in connection with registration under FIFRA, as amended, is acceptable. A stamped copy of the label is enclosed for your records.

Sincerely,

Sheryl K. Reilly, Ph.D.

Chief

Biochemical Pesticides Branch

Biopesticides and Pollution Prevention Division

7511C

	CONCURRENCES
SYMBOL ► 7511C	
SURNAME HULL	
DATE - 3 1104 EPA Form 1320-1 (12-70)	OFFICIAL FILE COPY 39



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MAR 1 2 2004

Nancy Huebl Wellmark International 1100 East Woodfield Road, Suite 500 Schaumburg, IL 60173

Sub:

RF-9811-EC

EPA Reg. No 2724-427

Your application dated July 21, 2003 to revise the directions for use and to add new uses (stored commodites) to the label as covered under the existing tolerance exemption

Dear Ms. Huebl:

The labeling amendment referred to above submitted in connection with registration under FIFRA, as amended, is acceptable. A stamped copy of the label is enclosed for your records.

Sincerely,

Sheryl K. Reilly, Ph.D

Chief

Biochemical Pesticides Branch

Biopesticides and Pollution Prevention Division

7511C

MASTER LABEL

[Optional text]

RF-9811 EC

Alternate Brand Names: DIACON® II (sublabel B); RIZACON™ (sublabel B); APEX® (sublabel C); STRIKE® Ultra Professional Midge Control (sublabel D); DIANEX® Emulsifiable Concentrate for Tobacco (sublabel A)

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth]

An Insect Growth Regulator

[to Control Insect Pests in Tobacco Processing and Storage Facilities]
[to Prevent the Emergence of Adult Sciarid Flies In Mushroom Culture]

[To Control Stored Product Insects in Stored Food Commodities, such as Cereal Grains, Grain Sorghum (Milo), Corn, Popcorn, Birdseed, Peanuts, Sunflower Seeds]

[to control insect pests in seeds]

[to Prevent the Emergence of Adult Filter Flies and Non-biting Midges in Waste Water Treatment Facilities]

ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6) OTHER INGREDIENTS*:

Total:

33.6%

66.4%

100.0%

This product contains 2.5 lbs/gallon (288 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements

EPA Reg. No. 2724-427

NET CONTENTS: 1 liter (33.8 fl oz)

2.5 liters (.66 gal)

MAR 1 2 2004 ### 2724-427

EPA Est. No.

^{*}Contains petroleum distillates

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

FIRST AID	
If in eyes	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
	Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes.
	Call a poison control center or doctor for treatment advice.
If on skin	Take off contaminated clothing. Rinse
	skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.
If swallowed	•
	Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give ANY liquid to the person. Do not give anything by mouth to an unconscious person.
center or doct	luct container or label with you when calling a poison control or, or going for treatment. You may also contact [phone mergency medical treatment information.
	YSICIAN: Contains petroleum distillate – vomiting may cause
aspiration pne	•

(Include WPS for APEX Mushroom Use pattern)

[Personal Protective Equipment(PPE):

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, such as neoprene rubber (\geq 14 mils), nitrile rubber (\geq 14 mils), barrier laminate, or viton (\geq 14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.]

[Engineering Controls Statements:

When handlers use closed systems or enclosed cabs in a manner that meets the

requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.]

[IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other_handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.]

[User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.]

ENVIRONMENTAL HAZARDS: (For Sublabel D only) Do not contaminate water when disposing of rinsate or equipment washwaters. (Sublabels A/B/C are indoor products – no Environmental Hazards statement required.)

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

[Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.]

[AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of4hours.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber (
 ≥ 14 mils), barrier laminate, or viton (≥ 14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.]

SUBLABEL A

(Directions for Use for RF-9811 EC [DIANEX]-Stored Tobacco Products) INTRODUCTION: RF-9811 EC is an emulsifiable formulation of the insect growth regulator, (S)-methoprene. It is designed for use in aerosol generators and as a concentrate for use as an aqueous spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead, it interferes with the normal processes of insect development and prevents adult emergence. RF-9811 EC, when used according to label directions, controls these and other insect pests: Almond moth (*Ephestia cautella*)

Cigarette beetle (Lasioderma serricorne)
Sawtooth grain beetle (Oryzaephilus surinamensis)
Red flour beetle (Tribolium castaneum)
Tobacco moth (Ephestia elutella)
Indian meal moth (Plodia interpunctella)
Lesser grain borer (Rhyzopertha dominica)
Merchant grain beetle (Oryzaephilus mercator)
Confused flour beetle (Tribolium confusum)
Warehouse beetle (Trogoderma spp.)

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Aerosol Generators: Apply RF-9811 EC as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply RF-9811 EC at the rate of 1 ml per 1,000 square feet as a surface treatment. For fogging applications, use 3 ml per 10,000 cubic feet.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before re-entry. Repeat application as required.

Application as an Aqueous Spray: To prepare a diluted spray solution, partially fill the mixing container with water, add 1 ml of RF-9811 EC, mix, and complete filling with a total of 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low-pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Use diluted spray solution within 72 hours of mixing. Agitate before each use. Repeat application as required.

SUBLABEL B

(Directions for Use for DIACON -Stored Product Insects)

PRODUCT INFORMATION: (S)-methoprene, the active ingredient in DIACON[®], protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, DIACON is not an adulticide, but its residual activity prevents the development of larvae into adults. DIACON, when used according to the label directions, prevents regeneration of these and other insect pests: almond moth, Indian meal moth, cigarette beetle, lesser grain borer, sawtooth grain beetle, merchant grain beetle, red flour beetle, and confused flour beetle. Treat existing insect populations with an adulticide before applying DIACON for residual protection.

Apply DIACON to any food commodity (including but not limited to: cereal grains, corn, sunflower, canola, popcorn, wheat, spices, sorghum, rice, cocoa, peanuts, oats, and millet) for control of insect larvae. DIACON may also be used to treat pet food, animal feedstuffs, birdseed, and cotton hulls. DIACON may be applied to seed stock. Treated commodities may be processed within 24 hours following an application.

If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain-damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

Stored Commodities: For protection of stored food, grain, animal feed, seeds used for oil, and seed stock against stored product insects - for optimum results, thoroughly clean and treat storage areas prior to storingcommodities. DIACON may also be applied as a top-dressing to stored products that have been placed into bins or storage areas. For top-dressing applications, spray or fog the bin headspace paying particular attention to the top of the commodity mass, beams, ceilings, and rafters. Thorough coverage is essential. For surface treatments, apply 1 ml (1/30 oz) of DIACON per 1,000 square feet; or for space spray, apply 3 ml (1/10 oz) per 10,000 cubic feet in sufficient diluent to provide adequate coverage. Do not flood top-dress area.

GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED: Dilute DIACON in water, FDA-approved food grade oils* or soybean oil and apply to the moving grain stream as a uniform coarse spray. Final water or oil dilution volume is 5 gallons of liquid per 1,000 bushels of grain and 10 gallons of liquid per 1,000 bushels of rice. Lower volumes of diluent may be used but, it is important to assure that the commodity mass is uniformly treated. Apply final spray volumes of oil solutions at the oil manufacturer's label application rates. Agitate water or oil solutions

A range of rates for different commodities is provided for flexibility during varying storage periods and conditions. For maximum residual, use higher rates; the lowest application rate offers shorter residual for commodities stored ≤ 6 months.

Apply DIACON in solution in accordance with the general directions, to stored products at the following rates per 1,000 bushels:

APPLICATION RATES

COMMODITY	fl oz	ml						
Wheat .	14	420	7	210	3.5	105	1.75	52
Corn	14	420	7	210	3.5	105	1.75	. 52
Sorghum (milo)	14	420	7	210	3.5	105	1.75	52
Barley	12	360	6	180	3.0	90	1.50	45
Rice	12	360	6	180	3.0	90	1.50	45
Oats	8	240	4	120	2.0	60	1.00	30
Peanuts*	8	240	4	120	2.0	60	1.00	30
Sunflower	8	240	4	120	2.0	60	1.00	30

^{*}For peanuts, use water solution only

To determine application rates for other commodities, contact your distributor or Wellmark International.

USE NOTES

- Apply DIACON grain protectant only to grain of known treatment history.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of DIACON to a spray tank partially filled with water or oil, mix, and complete filling with specified quantity of carrier.
- Use diluted spray solution within 72 hours of mixing. Agitate before each use.
- Clean up extremely dusty sites prior to application.
- DIACON may be used in metering systems in conjunction with dust-controlling oils. Follow the equipment and oil manufacturers' directions; ensure that the label rate of DIACON is applied uniformly.

DIACON may also be used as a fogging concentrate or surface spray for the treatment of stored product pests and other insect pests infesting warehouses, silos, storage bins or other stored commodity areas. DIACON may also be applied in food processing, food service, food preparation, and food handling establishments including, mills, bakeries, restaurants, taverns, industrial buildings, breweries, candy processing, pet food production, grocery stores, modes of transportation (rail cars, ships, and trucks), cereal processing and bottling facilities. In addition to treating raw commodities and associated processing facilities, DIACON may be applied to packaged, canned, and bottled foodstuffs, as well as associated packaging such as boxes, liners, and pallets. For application of DIACON as a fogging or space spray, use the following directions.

Application with Aerosol Generators: Apply DIACON as a mist or aerosol. Dilute with water or oil as required following the instructions of the spray equipment manufacturer. Apply DIACON at the rate of 1 ml (1/30 oz) per 1,000 square feet of surface area or 3 ml (1/10 oz) per 10,000 cubic feet. Use appropriate spray equipment to achieve uniform coverage.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before re-entry. Repeat application as required.

Application as an Aqueous Spray: To prepare a diluted spray solution, partially fill the mixing container with water, add 1 ml (1/30 oz) of DIACON, mix, and complete filling with a total of 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low-pressure sprayer typically used for indoor applications. Treat all areas that may harbor insect pests. Use diluted spray solution within 72 hours of mixing. Agitate before each use. Repeat application as required.

When tank mixing DIACON with conventional adulticides, the more stringent label will apply. DIACON may also be used or mixed with diatomaceous earth or dust-controlling oils.

SUBLABEL C

(Directions for Use for APEX – Mushrooms)

(S)-methoprene, the active ingredient in APEX® insect growth regulator (IGR) is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of (S)-methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. APEX will prevent the emergence of adult sciarid flies when incorporated into the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adults present at the time of application will not be affected. If high adult populations are present initially, use of a conventional adulticide will ensure the best overall results. After treatment with APEX, larvae will continue to develop to the pupal stage where they will die. Estimation of adult fly populations should be no earlier than 2 weeks after treatment to assess the full benefit of APEX.

METHOD, RATE, AND TIMING OF APPLICATION: For best results, incorporate APEX in the mushroom growing medium.

Follow either METHOD A, METHOD B, METHOD C, OR METHOD D Application Instructions.

A. INCORPORATE IN CASING AT TIME OF CASING

Apply APEX at the rate of 5½ fluid ounces per 1,000 sq ft. Apply evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after placement.

B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

In Compost: Apply APEX at the rate of 5½ fl oz/1,000 sq ft in adequate water for even distribution. Spray or sprinkle on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

In Casing: Apply APEX at the rate of 2½ fl oz/1,000 sq ft. Apply evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a 16-day or longer spawn run, use a split application.

First Application, on compost: Apply APEX 12-13 days after spawning. Drench APEX evenly on the surface at the rate of 2¾ fl oz/1,000 sq ft in adequate water for even distribution.

Second Application, in casing: Apply APEX at the rate of 2% fl oz/1,000 sq ft. Apply evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS

First Application, in casing: Apply 5½ fl. oz. APEX per 1,000 sq ft in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

Second Application, on casing surface just prior to first break: Apply 2¾ fl. oz. APEX per 1,000 square feet in adequate water for even distribution as a surface drench prior to first break of mushrooms.

MIXING AND HANDLING INSTRUCTIONS

- 1. Add the measured amount of APEX to a spray tank partially filled with water, mix, and complete filling with specified quantity of water.
- 1. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

EFFECT ON MUSHROOMS

In most cases, treatment with APEX has a beneficial effect on mushroom yield through control of damaging sciarid fly larvae. The user can determine if reduced crop yields will occur under his own cultural conditions by conducting test treatments on small plots.

SUBLABEL D

Directions for Use for non-biting midges/filter flies

INTRODUCTION:

RF-9811 EC is a unique product that controls filter flies (*Psychoda* spp.), non-biting midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water treatment facilities. RF-9811 EC contains an insect growth regulator (IGR) that is effective on the developing stages of insect pests. RF-9811 EC does not kill adults but affects the larval stages as they grow and develop. RF-9811 EC stops the formation of pupae of insect pests, thereby eliminating adult populations.

RF-9811 EC stops the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.

MIXING AND HANDLING INSTRUCTIONS:

Partially fill spray container with water; then add the specified amount of RF-9811 EC, agitate, and complete filling with water. Agitate mildly during application. To agitate use recirculation pump, mixer, air pump, or other suitable equipment.

USE APPLICATIONS

Waste Water Treatment Facility Pests: Use RF-9811 EC in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

What to Expect in Waste Water Treatment Facilities Continuous Flow Sewage (waste water)

In order to achieve effective results, apply RF-9811 EC daily for 10 days. If applications are not made on a continuous basis, erratic results may occur. Following initial applications of RF-9811 EC, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be very noticeable within a 2 week period following continuous application. Due to varying conditions or heavy infestations, a longer period may be necessary to achieve control. Since the mode of action of RF-9811 EC is to prevent adult emergence, existing adults and pupae present at the time of initial application will complete their life cycle.

If application of RF-9811 EC is halted following population suppression, rebound of the population can be expected within 2 to 3 weeks after stopping application. For continuous suppression throughout the pest season, continue applications of RF-9811 EC.

Sludge or Solid Waste Applications

For solid waste applications, use 3 ounces per million gallons of sludge or solids. Apply dilution until the drying beds have been filled. Following filling of the drying beds, halt the application. Apply the dilution at the <u>influent</u> side as the sludge or solids enter into the drying beds. Application of RF-9811 EC to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.

METHODS OF APPLICATION

Waste Water Treatment Facilities: Dilute RF-9811 EC with water prior to use. Apply RF-9811 EC by using a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence appropriate product dilution. Prepare the desired volume of dilution to apply over a 6-8 hour period, or in cases of sludge beds, apply until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of RF-9811 EC over a 6-8 hour period.

APPLICATION RATE

Waste Water Treatment Pests:

Initial Application –Apply3.0 ounces of RF-9811 EC per 1 million gallons of sewage (waste water) in sufficient water to apply uniformly at the influent side .

Application to Waste Water – Trickling Filter: Apply 3 ounces of RF-9811 EC per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply the material. Apply at times of low periods of flow (typically evening through early morning hours) for 6-8 hours. Discontinue treatment during peak flow periods and repeat applications the following day during the low flow period. Continue this application method for 10 days or until suppression of pests is achieved. Repeat the application every 15 days or as necessary to control pests.

D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS

First Application, in casing: Apply 5½ fl. oz. APEX per 1,000 sq ft in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

Second Application, on casing surface just prior to first break: Apply 2¾ fl. oz. APEX per 1,000 square feet in adequate water for even distribution as a surface drench prior to first break of mushrooms.

MIXING AND HANDLING INSTRUCTIONS

- 1. Add the measured amount of APEX to a spray tank partially filled with water, mix, and complete filling with specified quantity of water.
- 1. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

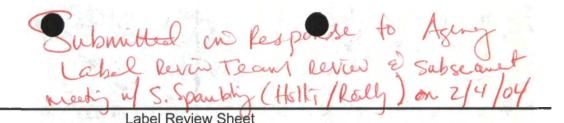
EFFECT ON MUSHROOMS

In most cases, treatment with APEX has a beneficial effect on mushroom yield through control of damaging sciarid fly larvae. The user can determine if reduced crop yields will occur under his own cultural conditions by conducting test treatments on small plots.

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BPB LABEL REVIEW TEAM	9
Product Name/EPA No./Application date: Zoecon R	2. F-342 Emula flable concontrate 127242
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Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

This product is toxic to [fish] [fish aquatic invertebrates] [oysters/shrimp] [fish, aquatic organisms, oysters and shrimp]. Drift and runoff may be hazardous to aquatic organisms in waters adjacent to treated areas.



FILENAME:

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amend 9811 add racs w

epa comments 204

PRODUCT:

RF9811 EC

COVERSHEET

UPDATE:

February 2004

EPA REG. NO.:

2724-427

APPROVED:

Submitted 7/03

SUPERSEDES:

11/09/01

OVERVIEW: Label amendment to add stored food commodities to DIACON section (based on 6/11/03(S)-Methoprene tolerance exemption – all tolerances revoked), clarify use directions for DIANEX/DIACON/waste water pests sections, included directions for additional application method on APEX/waste water pests sections

Page #	Description of Major Changes
1	Per EPA comments: added "Master Label" header, and identified sublabels for appropriate alternate brand names Revised stored product pests claim to include stored food commodities (based on 6/11/03 (S)-Methoprene tolerance exemption – all tolerances revoked) and added claim for seed pests "Per unit volume of active ingredient" revised based on specific gravity Per EPA comment: Net Contents – added specific figures
3	Per EPA comment: Environmental Hazards – Sublabels A/B/C are indoor use pattern therefore, no Environmental Hazards statement required. Sublabel D – This is a waste water treatment use pattern therefore a "Do not apply to water" statement not applicable. Per EPA comment: Moved Directions for Use heading and "It is a violation" statement to precede WPS language and Ag Use box
DIANEX section	n
5	Per EPA comments: added header – Sublabel A Moved Directions for Use heading and "It is a violation" statement to page 3 Directions for Use –reworded for clarity, Mixing Instructions incorporated into "Application as an Aqueous Spray"
DIACON sectio	n

Wellmark les parse

6-8	Per EPA comments: Per EPA comments: added header – Sublabel B Moved Directions for Use heading and "It is a violation…" statement to page 3
	In General Directions for Treatment of Grain Being Stored paragraph, in second sentence, removed word "Suggested"
	"Use Precautions" changed to "Use Notes"
	Directions for Use – Reworded for clarity
	Include stored food commodities (based on 6/11/03 (S)-Methoprene tolerance exemption – all tolerances revoked)
	Application Rate table – added commodities and
	proportionately expanded
	Added food processing sites (based on 6/11/03 (S)-Methoprene
	tolerance exemption – all tolerances revoked)
	Mixing Instructions incorporated into "Application
	as an Aqueous Spray"
	Added tank mixing text
APEX section	
9-10	Per EPA comments: Per EPA comments: added header – Sublabel C
	In Method, Rate and Timing of Application section,
	added "or Method D" to "Follow either Method A,
	Method B, Method C" sentence
	Directions for Use – additional application method
Waste water tre	eatment facility pests – non-biting midges/filter flies
11-13	Per EPA comments: Per EPA comments: added header – Sublabel D
	Moved Directions for Use heading and "It is a violation"
	statement to page 3
	Added Introduction paragraph to explain how product works
	Directions for Use: reworded for clarity
	Additional directions for application via trickling filter
	 deleted maintenance rate
13	Per EPA comment: Storage/Disposal put in box format

MASTER LABEL
[Optional text]

RF-9811 EC

Alternate Brand Names: DIACON® II; RIZACON™, APEX®; STRIKE® Ultra
Professional Midge Control; DIANEX® Emulsifiable Concentrate for Tobacco

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth]

An Insect Growth Regulator

[to Control Insect Pests in Tobacco Processing and Storage Facilities]

[to Prevent the Emergence of Adult Sciarid Flies In Mushroom Culture]

[To Control Stored Product Insects in Stored Food Commodities, such as Cereal Grains, Grain Sorghum (Milo), Corn, (except Sweet Corn and Popcorn),

Birdseed, and Peanuts, Sunflower Seeds]

[to control insect pests in seeds]

[to Prevent the Emergence of Adult Filter Flies and Non-biting Midges in Waste Water Treatment Facilities]

ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6)	33.6%
OTHER INGREDIENTS*:	66.4%
Total:	100.0%

^{*}Contains petroleum distillates

This product contains 2.5 lbs/gallon (300-288 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements

EPA Reg. No. 2724-427

EPA Est. No.

NET CONTENTS:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

	FIRST AID
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or doctor for treatment advice.
lf on skin	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If swallowed	 Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give ANY liquid to the person. Do not give anything by mouth to an unconscious person.
Have the produ	uct container or label with you when calling a poison control
	or, or going for treatment. You may also contact [phone
number] for en	nergency medical treatment information.
	YSICIAN: Contains petroleum distillate – vomiting may cause
aspiration pne	umonia.

(Include WPS for APEX Mushroom Use pattern)

[Personal Protective Equipment (PPE):

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber (≥ 14 mils), barrier laminate, or viton (≥ 14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry! wash PPE separately from other laundry.]

[Engineering Controls Statements:

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.1

[IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.]

[User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.]

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of rinsate or equipment washwaters.

[Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.]

[AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber (≥ 14 mils), barrier laminate, or viton (≥ 14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.]

Jub (abel 9

(Directions for Use for RF-9811 EC [DIANEX]-Stored Tobacco Products) INTRODUCTION: RF-9811 EC is an emulsifiable formulation of the insect growth regulator, (S)-methoprene. It is designed for use in cold-aerosol generators and as a concentrate for use as an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead, it interferes with the normal processes of insect development and prevents adult emergence. RF-9811 EC, when used according to label directions, controls these and other following insects pests:

Almond moth (Ephestia cautella)
Cigarette beetle (Lasioderma serricorne)
Sawtooth grain beetle (Oryzaephilus surinamensis)
Red flour beetle (Tribolium castaneum)
Tobacco moth (Ephestia elutella)
Indian meal moth (Plodia interpunctella)
Lesser grain borer (Rhyzopertha dominica)
Merchant grain beetle (Oryzaephilus mercator)
Confused flour beetle (Tribolium confusum)
Warehouse beetle (Trogoderma spp.)

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DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Celd-Aerosol Generators: Apply RF-9811 EC as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply RF-9811 EC at the rate of 1 ml per 1,000 square feet of surface area as a surface treatment. For fogging applications, use 3 ml per 10,000 cubic feet. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before re-entry. Repeat application as required.

Application as an Aqueous Spray: To Pprepare a diluted spray solution, by partially fill the mixing container with water, adding 1 ml of RF-9811 EC, to mix, and complete filling with a total of 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low-pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Use diluted spray solution within 72 hours of mixing. Agitate before each use. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add RF-9811 EC, mix and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.



(Directions for Use for DIACON -Stored Product Insects)

PRODUCT INFORMATION: (S)-methoprene, the active ingredient in DIACON®, protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, DIACON is not an adulticide, but its residual activity prevents the development of larvae into adults. DIACON, when used according to the label directions, prevents regeneration of these and other following insects pests: almond moth, Indian meal moth, cigarette beetle, lesser grain borer, sawtooth grain beetle, merchant grain beetle, red flour beetle, and confused flour beetle. Treat existing insect populations with an adulticide before applying DIACON for residual protection.

Apply DIACON to any food commodity (including but not limited to: cereal grains, corn, sunflower, canola, popcorn, wheat, spices, sorghum, rice, cocoa, peanuts, oats, and millet) for control of insect larvae. DIACON may also be used to treat pet food, animal feedstuffs, birdseed, and cotton hulls. DIACON may be applied to seed stock. Treated commodities may be processed within 24 hours following an application.

If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain-damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

Stored CommoditiesGrain: For protection of stored food, grain, animal feed, seeds used for oil, and seed grains-stock against stored product grain-insects - for optimum results, thoroughly clean and treat grain-storage areas prior to storingage of graincommodities. DIACON may also be applied as a top-dressing to stored products that have already been placed into bins or storage areas. Use the rate of 2.5 - 5 ppm for this type of application. For topdressing applications, spray or fog the bin headspace paying particular attention to the top of the commodity mass, beams, ceilings, and rafters. Thorough coverage is essential. For surface treatments, apply 1 ml (1/30 oz) of DIACON per 1,000 square feet; or for space spray, apply 3 ml (1/10 oz) per 10,000 cubic feet in sufficient diluent to provide adequate coverage. Do not flood top-dress area.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Delete

GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED: Dilute DIACON with-in water, or FDA-approved food grade oils* or soybean oil and apply to the moving grain stream as a uniform coarse spray to give a deposit of 5 ppm of DIACON on the grain. Use a daggested final water or oil dilution solution volume of is 5 gallons of tiquid per 1,000 bushels of grain and 10 gallons of liquid per 1,000 bushels of rice. Lower volumes of diluent may be used but, it is important to assure that the commodity mass is uniformly treated. Apply final spray volumes of oil solutions at the oil manufacturer's label application rates. Agitateion of water or oil solutions is necessary.

A range of rates for different commodities is provided for flexibility during varying storage periods and conditions. For maximum residual and efficacy, use the higher rates; the lowest application rate offers shorter residual for commodities stored ≤ 6 months of 5 ppm. For shorter term residual, lower rates may apply, but do not use rates less than 1 ppm.

Apply DIACON is to be applied in solution in accordance with the general directions, to stored products at the following rates per 1,000 bushels: to provide treatment with 5 ppm concentrations of DIACON. When using lower rates, use the appropriate amount of formulation to achieve the desired application rate:

	5 ppm		2.5 ppm		1 ppm	
	floz	ml	fl oz	ml	fl oz	ml
Wheat	7.70	228	4.0	114	1.54	46
Corn	7.10	212	3.5	106	1.42	43
Grain sorghum (Milo)	7.10	212	3.5	106	1.42	43
Barley	6.10	182	3.0	91	1.22	37
Rice	5.70	170	3.0	85		34
Oats	4.10	121	2.0	61	0.80	25
Peanuts*	3.85	115	2.0	60	0.80	24

*For peanuts, use water solution only APPLICATION RATES

COMMODITY	fl oz	ml	fl oz	ml	fl oz	ml	fl oz	ml
Wheat	14	420	7	210	3.5	105	1.75	52
Corn	14	420	7	210	3.5	105	1.75	52
Sorghum (milo)	14	420	7	210	3.5	105	1.75	52
Barley	12	360	6	180	3.0	90	1.50	45
Rice	12	360	6	180	3.0	90	1.50	45
Oats	8	240	4	120	2.0	60	1.00	30
Peanuts*	8	240	4	120	2.0	60	1.00	30
Sunflower	8	240	4	120	2.0	60	1.00	30

^{*}For peanuts, use water solution only

To determine application rates for other commodities, contact your distributor or Wellmark International.

Notes

USE PRECAUTIONS:

- Apply DIACON grain protectant only to grain of known treatment history, apply no more than once per crop.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of DIACON to a spray tank partially filled with water or mineral oil, mix, and complete filling with specified quantity of carrier.
- Use diluted spray solution within 48-72 hours of mixing. Agitate before each use.
- Do not treat at Clean up extremely dusty sites prior to application.
- DIACON may be used in metering systems in conjunction with dust-controlling oils.
 Follow the equipment and oil manufacturers' directions; ensure that the label rate of DIACON is applied uniformly.

DIACON may also be used as a fogging concentrate or surface spray for the treatment of stored product pests and other insect pests infesting warehouses, silos, storage bins or other stored commodity areas. DIACON may also be applied in food processing, food service, food preparation, and food handling establishments including, mills, bakeries, restaurants, taverns, industrial buildings, breweries, candy processing, pet food production, grocery stores, modes of transportation (rail cars, ships, and trucks), cereal processing and bottling facilities. In addition to treating raw commodities and associated processing facilities, DIACON may be applied to packaged, canned, and bottled foodstuffs, as well as associated packaging such as boxes, liners, and pallets. For application of DIACON as a fogging or space spray, use the following directions.

Application with Cold-Aerosol Generators: Apply DIACON as a mist or aerosol. Dilute with water or oil as required following the instructions of the spray equipment manufacturer. Apply DIACON at the rate of 1 ml (1/30 oz) per 1,000 square feet of surface area or +3 ml (1/10 oz) per 10,000 cubic feet. Use appropriate spray equipment to achieve uniform treatmentcoverage.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before re-entry. Repeat application as required.

Application as an Aqueous Spray: To Pprepare a diluted spray solution, by partially fill the mixing container with water, adding 1 ml (1/30 oz) of DIACON, mix, and complete filling with a total ofte 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low-pressure sprayer typically used for indoor applications. Treat all areas which-that may harbor insect pests. Use diluted spray solution within 72 hours of mixing. Agitate before each use. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add DIACON, mix and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

When tank mixing DIACON with conventional adulticides, the more stringent label will apply. DIACON may also be used or mixed with diatomaceous earth or dust-controlling oils.

(Directions for Use for APEX – Mushrooms) (S)-methoprene, the active ingredient in APEX® insect growth regulator (IGR) is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of (S)-methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. APEX will prevent the emergence of adult sciarid flies when incorporated into the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adults present at the time of application will not be affected. If high adult populations are present initially, use of a conventional adulticide will ensure the best overall results. After treatment with APEX, larvae will continue to develop to the pupal stage where they will die. Estimation of adult fly populations should be no earlier than 2 weeks after treatment to assess the full benefit of APEX.

METHOD, RATE, AND TIMING OF APPLICATION: For best results, incorporate APEX in the mushroom growing medium.

Follow either METHOD A, METHOD B, METHOD C, or method D Application Instructions.

A. INCORPORATE IN CASING AT TIME OF CASING
Apply APEX at the rate of 5½ fluid ounces per 1,000 sq ft (fl-oz/1,000 sq ft). Make
aApplyication evenly and mechanically mix into casing material prior to the casing
operation, or drench evenly onto the surface of the casing immediately after
placement.

B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

In Compost: Apply APEX at the rate of 5½ fl oz/1,000 sq ft in adequate water for even distribution. Spray or sprinkle on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

In Casing: Apply APEX at the rate of 2½ fl oz/1,000 sq ft. Make aApplyication evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a 16-day or longer spawn run, use a split application ean be used.

First Application, on compost: Apply APEX 12-13 days after spawning. Drench APEX evenly on the surface at the rate of 2¾ fl oz/1,000 sq ft in adequate water for even distribution.

Second Application, in casing: Apply APEX at the rate of 2¾ fl oz/1,000 sq ft. Make aApplyication evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS

First Application, in casing: Apply 5½ fl. oz. APEX per 1,000 sq ft in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

Second Application, on casing surface just prior to first break: Apply 2% fl. oz. APEX per 1,000 square feet in adequate water for even distribution as a surface drench prior to first break of mushrooms.

- MIXING AND HANDLING INSTRUCTIONS

 1. Add the measured amount of APEX to a spray tank partially filled with water, mix, and complete filling with specified quantity of water.
- 2. Use diluted spray solution within 48-72 hours of mixing. Agitate before each use.

EFFECT ON MUSHROOMS

In most cases, treatment with APEX has a beneficial effect on mushroom yield through control of damaging sciarid fly larvae. The user can determine if reduced crop yields will occur under his own cultural conditions by conducting test treatments on small plots.

Directions for Use for non-biting midges/filter flies

INTRODUCTION:

RF-9811 EC is a unique product that controls filter flies (*Psychoda* spp.), non-biting midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water treatment facilities. RF-9811 EC contains an insect growth regulator (IGR) that is effective on the developing stages of insect pests. RF-9811 EC does not kill adults but affects the larval stages as they grow and develop. RF-9811 EC stops the formation of pupae of insect pests, thereby eliminating adult populations. RF-9811 EC stops the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

MIXING AND HANDLING INSTRUCTIONS:

Partially fill spray container with water; then add the specified amount of RF-9811 EC, agitate, and complete filling with water. Agitate mildly during application. To Aagitateien can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

USE APPLICATIONS

Waste Water Treatment Facility Pests: Use RF-9811 EC in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

What to Expect in Waste Water Treatment Facilities Continuous Flow Sewage (waste water)

In order to achieve effective results, apply RF-9811 EC must be applied daily for 10 daysat least 2 weeks. If applications are not made on a continuous basis, erratic results may occur. Following initial applications of RF-9811 EC, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be very noticeable within a 2 week period following continuous application. Due to varying conditions or heavy infestations, a longer period may be necessary for to achieve control. Since the mode of action of RF-9811 EC is to prevent adult emergence, existing adults and pupae present at the time of initial application will complete their life cycle.

As adult suppression peaks, use a maintenance rate of RF-9811 EC for continuous protection from population rebound. However, ilf application of RF-9811 EC is halted following population suppression, rebound of the population can be expected within 2 to 3 weeks after stopping application. For continuous suppression throughout the pest season, continue applications of RF-9811 EC.

Sludge or Solid Waste Applications

For solid waste applications, use 3 ounces per million gallons of sludge or solids the initial high-rate. Apply dilution until the drying beds have been filled. Following filling of the drying beds, halt the dilution-application. Make aApplyications of the dilution at the influent side as the sludge or solids enter into the drying beds. Application of RF-9811 EC to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.

METHODS OF APPLICATION

Waste Water Treatment Facilities: Dilute RF-9811 EC with water prior to use. Apply RF-9811 EC by using a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence appropriate product dilution. Depending on the desage rate, pPrepare the desired volume of dilution to apply over a 246-8 hour period (day tank), or in cases of sludge beds, applyied until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of RF-9811 EC over a 24-6-8 hour period. Mix sufficient material in advance to provide for applications longer than 24 hours. Metering pumps that are capable of delivering material for more than 24 hours will provide best results.

APPLICATION RATE

Waste Water Treatment Pests:

Initial Application — Apply 2.5 to 3.0 ounces of RF-9811 EC per 1 million gallons of sewage (waste water) in sufficient water to apply uniformly at the influent side over a 24 hour period.

Application to Waste Water – Trickling Filter: Apply 3 ounces of RF-9811 EC per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply the material. Apply at times of low periods of flow (typically evening through early morning hours) for 6-8 hours. Discontinue treatment during peak flow periods and repeat applications the following day during the low flow period. Continue this application method for 10 days or until suppression of pests is achieved. Repeat the application every 15 days or as necessary to control pests.

Maintenance Rate - 1.5 to 2.0 ounces RF-9811 EC per 1 million gallons of sewage (waste water) in sufficient water to apply uniformly at the influent side over a 24 hour period.

To achieve effective results, use initial application rates on a daily basis for 2 weeks, without interruption. Use sufficient water/RF-9811 EC to achieve uniform application to sewage (waste water) over a 24 hour period. Make application of the dilution at the influent side of the particular area to be treated.]

Maintain initial rate of application for 2 weeks and then for continued effectiveness, follow the directions for the maintenance rate.

APPLICATION SITES

Waste Water Treatment Facilities: Make a Applyications of RF-9811 EC to sewage as it flows into trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem.

Make-Apply RF-9811 EC applications as the sewage enters (influent areas) the targeted processing area. Failure to add the material For best results, apply at the influent side may result in erratic results.

STORAGE and DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Storage - Store in a cool dry place. Pesticide Disposal - Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, expressed or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

APEX®, DIACON II®, STRIKE®, and DIANEX®, are registered trademarks of Wellmark International.

Wellmark International Schaumburg IL 60173

Made in USA

For information or in case of an emergency, call 1-800-XXX-XXXX. Visit our Web site: [web site address]

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Regulatory Type: Product Registration - Section 3	Resubmission, C Yes C No	Print Letter
Application Type: Amendment		Enter More Information
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Risk Manager: Biologicals & Pollution Prevention Division	n, PM Team 91	adention for (Shreet con
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	New Ingredient Received Date	
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

August 1, 2003

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

NANCY HUEBL WELLMARK INTERNATIONAL 1100 EAST WOODFIELD ROAD, SUITE 500 SCHAUMBURG, IL 60173

PRODUCT NAME: RF-9811 EC

COMPANY NAME: WELLMARK INTERNATIONAL

EPA FILE SYMBOL: 2724-427 EPA RECEIPT DATE: 07/29/03

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 308-8269.

Sincerely,

Front End Processing Staff

7-Wrice

Information Services Branch

Information Resources and Services Division



United States Environmental Protection Agency Washington, DC 20460

Registration Amendment Other

OPP Identifier Number

Company/Product Number			2. EPA Product M	anager		3	3. Proposed Cl	assification
Wellmark International/272	24-427		S. Reilly]		
4. Company/Product (Name)			PM #				X None	Restricted
Wellmark International/Zoecon RF-342 Emulsifiable		Biopesticides					Leanicied	
	oncentrate		Бюровников					
5. Name and Address of Applic	ant / Registrant (Include ZIP	Code)	6. Expedited F	Review. In	accordance with	FIFRA	Section 3(C)	(3)
Wellmark International			(b)(i), my produ	uct is similar o	or identical in co	mpositio	n and labelii	ng to:
1100 East Woodfiel Road	•		EPA Reg. No					
Schaumburg, Illinois 601	73							
			Product Name					
Check if this is a	new address							
			Section - II					
X Amendment - Explain belo	N4(Final printed la	bels in response t	0		
Amendment - Explain belo	····		با	Agency letter of	iated			
Resubmission in response	to Agency letter dated			"Me Too" Appl	ication			
Notification - Explain below	 v			Other - Explain	n below			
Notification - Explain below	·-							
Explanation: Use addition	nal page(s) if necessary. (Fo	r section 1 and	section II.)					. —
Label amendment to add s				n 6/11/03 (S)-	-Methoprene tol	erance e	xemption - a	ill tolerances
revoked), clarify use direct	ions for DIANEX/DIACO	N/waste wat	er pests sections, include	d directions for	or additional app	olication	method on A	APEX/waste
water pests sections								
			Section - III					
1. Material This Product Will	be Packaged In:					<u> </u>		
Child-Resistant Packaging	Unit Packaging		Water Soluble Packagir	ıg	2. Type of Con	tainer		
	Yes		Yes		X Meta	- 1		
Yes	X No		X No		X Plas			
X No	<u> </u>				X Glas	ss		
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3. Location of Net Contents Info	ormation	4. Size(s) Reta	ail Container	510	cation of Label Dir	rections		
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X Label Co	ontainer	1-2.5 liters	•	E	On Label Ad	companyi	ing Product	
6. Manner in Which Label is Af	fixed to Product		ograph	Other				
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1. Contact Point (Complete	nems airectly below for ide	entification of		ıı necessary, t	1			Aroa Cada)
Name Nancy Huebl			Title			ı elepnone (847) 330	No. (Include :	Alea Code)
reality ridebi			Regulatory Specialist					
	Certification 6. Date Application					olication		
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I								
acknowledge that any knowingly false or misleading statements my be punishable by fine or imprisonment or both under applicable law. (Stamped)								
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Application for Pesticide - Section I

Wellmark

July 21, 2003

Document Processing Desk (AMEND)
Office of Pesticide Programs 7504C
U.S. Environmental Protection Agency
Room 266A Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

ATTENTION: Sheryl Reilly, Biopesticides

SUBJECT: LABEL AMENDMENT: ADD FOOD COMMODITIES (RAC'S),

REVISE DIRECTIONS FOR USE

ZOECON® RF-342 EMULSIFIABLE CONCENTRATE (RF9811 EC)

EPA REG. NO. 2724-427

Dear Ms. Reilly:

Enclosed is completed EPA Form 8570-1 and 5 copies of revised labeling for the above product. I've included one highlighted copy (red is new text; blue [strikeout] is deleted text) for your convenience in reviewing noted changes. This amendment is being submitted as a result of the June 11, 2003 finalization of the (S)-Methoprene tolerance exemption whereby (S)-Methoprene can now be used on all Flaw Agricultural Commodities (RAC's). This "master label" is composed of 4 different sets of Directions for Use (DIANEX(stored tobacco pests)/DIACON (stored product insects)/APEX (mushroom sciarid flies)/waste water treatment (non-biting midges/filter flies). We are taking this opportunity to add stored food commodities (RAC's) (sweet corn, sunflower seeds, seeds used for oil, seed stock, spices, cocoa) as well as pet food and animal feed to the DIACON - for stored product insects directions. Directions for Use for all sections of the label are being revised for clarity; as well as including additional application methods. All of the changes are more specifically denoted on the highlighted label cover sheet.

If you have any questions, please, call me directly at 847-330-5376 or contact me via email (nancy.huebl@wellmarkint.com). Thank you for your assistance in this matter.

Yours sincerely, WELLMARK INTERNATIONAL

Many Suebl

Nancy Huebl

Regulatory Specialist

enclosure

cc: C. Elmi/J. Richardson

Label Review Sheet

FILENAME: g:\regulatory\LABELS\

CAHSPEC\02724427\

COVERSHEET UPDATE:

July 2003

amend 9811 add racs 703

PRODUCT:

RF9811 EC

EPA REG. NO.:

2724-427

APPROVED:

Submitted 7/03

SUPERSEDES:

11/09/01

OVERVIEW: Label amendment to add stored food commodities to DIACON section (based on 6/11/03 (S)-Methoprene tolerance exemption – all tolerances revoked), clarify use directions for DIANEX/DIACON/waste water pests sections, included directions for additional application method on APEX/waste water pests sections

Page #	Description of Major Changes
1	Revised stored product pests claim to include stored food commodities (based on 6/11/03 (S)-Methoprene tolerance exemption – all tolerances revoked) and added claim for seed pests
DIANEY	"Per unit volume of active ingredient" revised based on specific gravity
DIANEX se	
5	Directions for Use – reworded for clarity, Mixing Instructions incorporated into "Application as an Aqueous Spray"
DIACON se	ction
6-8	Directions for Use - Reworded for clarity
	Include stored food commodities (based on 6/11/03 (S)-Methoprene
	tolerance exemption – all tolerances revoked)
	Application Rate table – added commodities and
	proportionately expanded
	Added food processing sites (based on 6/11/03 (S)-Methoprene
	tolerance exemption - all tolerances revoked)
	Mixing Instructions incorporated into "Application
	as an Aqueous Spray"
	Added tank mixing text
APEX secti	on
9-10	Directions for Use – additional application method
Waste water	er treatment facility pests – non-biting midges/filter flies

11-13	Added Introduction paragraph to explain how product works
	Directions for Use: reworded for clarity
	Additional directions for application via trickling filter
	 deleted maintenance rate

[Optional text]

RF-9811 EC

Alternate Brand Names: DIACON® II; RIZACON™, APEX®; STRIKE® Ultra Professional Midge Control; DIANEX® Emulsifiable Concentrate for Tobacco

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth]

An Insect Growth Regulator

[to Control Insect Pests in Tobacco Processing and Storage Facilities]

[to Prevent the Emergence of Adult Sciarid Flies In Mushroom Culture]

[To Control Stored Product Insects in Stored Food Commodities, such as Cereal Grains, Grain Sorghum (Milo), Corn, Popcorn, Birdseed, Peanuts, Sunflower Seeds]

[to control insect pests in seeds]

[to Prevent the Emergence of Adult Filter Flies and Non-biting Midges in Waste Water Treatment Facilities]

ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6)	33.6%
OTHER INGREDIENTS*:	
Total:	

^{*}Contains petroleum distillates

This product contains 2.5 lbs/gallon (288 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements

EPA Reg. No. 2724-427

NET CONTENTS:

EPA Est, No.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

	FIRST AID
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or doctor for treatment advice.
If on skin	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If swallowed	Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give ANY liquid to the person. Do not give anything by mouth to an unconscious person.
	uct container or label with you when calling a poison control
	or, or going for treatment. You may also contact [phone
	nergency medical treatment information.
	YSICIAN: Contains petroleum distillate – vomiting may cause
aspiration pne	umonia.

(Include WPS for APEX Mushroom Use pattern)

[Personal Protective Equipment (PPE):

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber (≥ 14 mils), barrier laminate, or such as neoprene rubber (≥ 14 mils). viton (≥ 14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.]

[Engineering Controls Statements:

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.]

[IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.]

[User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.]

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of rinsate or equipment washwaters.

[Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.]

[AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber
 (≥ 14 mils), barrier laminate, or viton (≥ 14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.]

(Directions for Use for RF-9811 EC [DIANEX]-Stored Tobacco Products) INTRODUCTION: RF-9811 EC is an emulsifiable formulation of the insect growth regulator, (S)-methoprene. It is designed for use in aerosol generators and as a concentrate for use as an aqueous spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead, it interferes with the normal processes of insect development and prevents adult emergence. RF-9811 EC, when used according to label directions, controls these and other insect pests: Almond moth (Ephestia cautella) Cigarette beetle (Lasioderma serricorne) Sawtooth grain beetle (Oryzaephilus surinamensis) Red flour beetle (*Tribolium castaneum*) Tobacco moth (Ephestia elutella) Indian meal moth (Plodia interpunctella) Lesser grain borer (Rhyzopertha dominica) Merchant grain beetle (Oryzaephilus mercator) Confused flour beetle (Tribolium confusum) Warehouse beetle (Trogoderma spp.)

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Aerosol Generators: Apply RF-9811 EC as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply RF-9811 EC at the rate of 1 ml per 1,000 square feet as a surface treatment. For fogging applications, use 3 ml per 10,000 cubic feet.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before re-entry. Repeat application as required.

Application as an Aqueous Spray: To prepare a diluted spray solution, partially fill the mixing container with water, add 1 ml of RF-9811 EC, mix, and complete filling with a total of 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low-pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Use diluted spray solution within 72 hours of mixing. Agitate before each use. Repeat application as required.

(Directions for Use for DIACON -Stored Product Insects)

PRODUCT INFORMATION: (S)-methoprene, the active ingredient in DIACON[®], protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, DIACON is not an adulticide, but its residual activity prevents the development of larvae into adults. DIACON, when used according to the label directions, prevents regeneration of these and other insect pests: almond moth, Indian meal moth, cigarette beetle, lesser grain borer, sawtooth grain beetle, merchant grain beetle, red flour beetle, and confused flour beetle. Treat existing insect populations with an adulticide before applying DIACON for residual protection.

Apply DIACON to any food commodity (including but not limited to: cereal grains, corn, sunflower, canola, popcorn, wheat, spices, sorghum, rice, cocoa, peanuts, oats, and millet) for control of insect larvae. DIACON may also be used to treat pet food, animal feedstuffs, birdseed, and cotton hulls. DIACON may be applied to seed stock. Treated commodities may be processed within 24 hours following an application.

If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain-damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

Stored Commodities: For protection of stored food, grain, animal feed, seeds used for oil, and seed stock against stored product insects - for optimum results, thoroughly clean and treat storage areas prior to storing commodities. DIACON may also be applied as a top-dressing to stored products that have been placed into bins or storage areas. For topdressing applications, spray or fog the bin headspace paying particular attention to the top of the commodity mass, beams, ceilings, and rafters. Thorough coverage is essential. For surface treatments, apply 1 ml (1/30 oz) of DIACON per 1,000 square feet; or for space spray, apply 3 ml (1/10 oz) per 10,000 cubic feet in sufficient diluent to provide adequate coverage. Do not flood top-dress area.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED: Dilute DIACON in water, FDA-approved food grade oils*, or soybean oil and apply to the moving grain stream as a uniform, coarse spray. Suggested final water or oil dilution volume is 5 gallons of liquid per 1,000 bushels of grain and 10 gallons of liquid per 1,000 bushels of rice. Lower volumes of diluent may be used but, it is important to assure that the commodity mass is uniformly treated. Apply final spray volumes of oil solutions at the oil manufacturer's label application rates. Agitate water or oil solutions.

A range of rates for different commodities is provided for flexibility during varying storage periods and conditions. For maximum residual, use higher rates; the lowest application rate offers shorter residual for commodities stored \leq 6 months.

Apply DIACON in solution in accordance with the general directions, to stored products at the following rates per 1,000 bushels:

APPLICATION RATES

COMMODITY	fl oz	ml	fl oz	ml	fl oz	ml	fl oz	ml
Wheat	14	420	7	210	3.5	105	1.75	52
Corn	14	420	7	210	3.5	105	1.75	52
Sorghum (milo)	14	420	7	210	3.5	105	1.75	52
Barley	12	360	6	180	3.0	90	1.50	45
Rice	12	360	6	180	3.0	90	1.50	45
Oats	8	240	4	120	2.0	60	1.00	30
Peanuts*	8	240	4	120	2.0	60	1.00	30
Sunflower	8	240	4	120	2.0	60	1.00	30

^{*}For peanuts, use water solution only

To determine application rates for other commodities, contact your distributor or Wellmark International.

USE PRECAUTIONS:

- Apply DIACON grain protectant only to grain of known treatment history.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of DIACON to a spray tank partially filled with water or oil, mix, and complete filling with specified quantity of carrier.
- Use diluted spray solution within 72 hours of mixing. Agitate before each use.
- Clean up extremely dusty sites prior to application.
- DIACON may be used in metering systems in conjunction with dust-controlling oils.
 Follow the equipment and oil manufacturers' directions; ensure that the label rate of DIACON is applied uniformly.

DIACON may also be used as a fogging concentrate or surface spray for the treatment of stored product pests and other insect pests infesting warehouses, silos, storage bins or other stored commodity areas. DIACON may also be applied in food processing, food service, food preparation, and food handling establishments including, mills, bakeries, restaurants, taverns, industrial buildings, breweries, candy processing, pet food production, grocery stores, modes of transportation (rail cars, ships, and trucks), cereal processing and bottling facilities. In addition to treating raw commodities and associated processing facilities, DIACON may be applied to packaged, canned, and bottled foodstuffs, as well as associated packaging such as boxes, liners, and pallets. For application of DIACON as a fogging or space spray, use the following directions.

Application with Aerosol Generators: Apply DIACON as a mist or aerosol. Dilute with water or oil as required following the instructions of the spray equipment manufacturer. Apply DIACON at the rate of 1 ml (1/30 oz) per 1,000 square feet of surface area or 3 ml (1/10 oz) per 10,000 cubic feet. Use appropriate spray equipment to achieve uniform coverage.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before re-entry. Repeat application as required.

Application as an Aqueous Spray: To prepare a diluted spray solution, partially fill the mixing container with water, add 1 ml (1/30 oz) of DIACON, mix, and complete filling with a total of 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low-pressure sprayer typically used for indoor applications. Treat all areas that may harbor insect pests. Use diluted spray solution within 72 hours of mixing. Agitate before each use. Repeat application as required.

When tank mixing DIACON with conventional adulticides, the more stringent label will apply. DIACON may also be used or mixed with diatomaceous earth or dust-controlling oils.

(Directions for Use for APEX – Mushrooms)
(S)-methoprene, the active ingredient in APEX® insect growth regulator (IGR) is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of (S)-methoprene does not result in immediate insect kill; it interferes with the normal process of insect development. APEX will prevent the emergence of adult sciarid flies when incorporated into the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adults present at the time of application will not be affected. If high adult populations are present initially, use of a conventional adulticide will ensure the best overall results. After treatment with APEX, larvae will continue to develop to the pupal stage where they will die. Estimation of adult fly populations should be no earlier than 2 weeks after treatment to assess the full benefit of APEX.

METHOD, RATE, AND TIMING OF APPLICATION: For best results, incorporate APEX in the mushroom growing medium.

Follow either **METHOD A**, **METHOD B**, or **METHOD C** Application Instructions.

A. INCORPORATE IN CASING AT TIME OF CASING

Apply APEX at the rate of 5½ fluid ounces per 1,000 sq ft. Apply evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after placement.

B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

In Compost: Apply APEX at the rate of 5½ fl oz/1,000 sq ft in adequate water for even distribution. Spray or sprinkle on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

In Casing: Apply APEX at the rate of 2½ fl oz/1,000 sq ft. Apply evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a 16-day or longer spawn run, use a split application.

First Application, on compost: Apply APEX 12-13 days after spawning. Drench APEX evenly on the surface at the rate of 2¾ fl oz/1,000 sq ft in adequate water for even distribution.

Second Application, in casing: Apply APEX at the rate of 2% fl oz/1,000 sq ft. Apply evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

D. INCORPORATE IN CASING AT TIME OF CASING FOLLOWED BY A SURFACE APPLICATION PRIOR TO FIRST BREAK OF MUSHROOMS

First Application, in casing: Apply 5½ fl. oz. APEX per 1,000 sq ft in adequate water for even distribution and mechanically mix into the casing material prior to the casing operation.

Second Application, on casing surface just prior to first break: Apply 2¾ fl. oz. APEX per 1,000 square feet in adequate water for even distribution as a surface drench prior to first break of mushrooms.

- MIXING AND HANDLING INSTRUCTIONS

 1. Add the measured amount of APEX to a spray tank partially filled with water, mix, and complete filling with specified quantity of water.
- 2. Use diluted spray solution within 72 hours of mixing. Agitate before each use.

EFFECT ON MUSHROOMSIn most cases, treatment with APEX has a beneficial effect on mushroom yield through control of damaging sciarid fly larvae. The user can determine if reduced crop yields will occur under his own cultural conditions by conducting test treatments on small plots.

Directions for Use for non-biting midges/filter flies

INTRODUCTION:

RF-9811 EC is a unique product that controls filter flies (*Psychoda* spp.), non-biting midges (*Chironomidae*), and other nuisance aquatic insect species infesting waste water treatment facilities. RF-9811 EC contains an insect growth regulator (IGR) that is effective on the developing stages of insect pests. RF-9811 EC does not kill adults but affects the larval stages as they grow and develop. RF-9811 EC stops the formation of pupae of insect pests, thereby eliminating adult populations. RF-9811 EC stops the cycle of reproduction, keeping pest infestations under control. Continued use of the product prevents these pests from rebounding into unmanageable infestations.

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

MIXING AND HANDLING INSTRUCTIONS:

Partially fill spray container with water; then add the specified amount of RF-9811 EC, agitate, and complete filling with water. Agitate mildly during application. To agitate, use recirculation pump, mixer, air pump, or other suitable equipment.

USE APPLICATIONS

Waste Water Treatment Facility Pests: Use RF-9811 EC in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

What to Expect in Waste Water Treatment Facilities Continuous Flow Sewage (waste water)

In order to achieve effective results, apply RF-9811 EC daily for 10 days. If applications are not made on a continuous basis, erratic results may occur. Following initial applications of RF-9811 EC, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be very noticeable within a 2 week period following continuous application. Due to varying conditions or heavy infestations, a longer period may be necessary to achieve control. Since the mode of action of RF-9811 EC is to prevent adult emergence, existing adults and pupae present at the time of initial application will complete their life cycle.

If application of RF-9811 EC is halted following population suppression, rebound of the population can be expected within 2 to 3 weeks after stopping application. For continuous suppression throughout the pest season, continue applications of RF-9811 EC.

Sludge or Solid Waste Applications

For solid waste applications, use 3 ounces per million gallons of sludge or solids. Apply dilution until the drying beds have been filled. Following filling of the drying beds, halt the application. Apply the dilution at the <u>influent</u> side as the sludge or solids enter into the drying beds. Application of RF-9811 EC to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.

METHODS OF APPLICATION

Waste Water Treatment Facilities: Dilute RF-9811 EC with water prior to use. Apply RF-9811 EC by using a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence appropriate product dilution. Prepare the desired volume of dilution to apply over a 6-8 hour period, or in cases of sludge beds, apply until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of RF-9811 EC over a 6-8 hour period.

APPLICATION RATE

Waste Water Treatment Pests:

Initial Application – Apply 3 ounces of RF-9811 EC per 1 million gallons of sewage (waste water) in sufficient water to apply uniformly at the influent side.

Application to Waste Water – Trickling Filter: Apply 3 ounces of RF-9811 EC per 1 million gallons of sewage [waste water] in sufficient water to uniformly apply the material. Apply at times of low periods of flow (typically evening through early morning hours) for 6-8 hours. Discontinue treatment during peak flow periods and repeat applications the following day during the low flow period. Continue this application method for 10 days or until suppression of pests is achieved. Repeat the application every 15 days or as necessary to control pests.

APPLICATION SITES

Waste Water Treatment Facilities: Apply RF-9811 EC to sewage as it <u>flows into</u> trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem.

Apply RF-9811 EC as the sewage enters (influent areas) the targeted processing area. For best results, apply at the influent side .

STORAGE and DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Storage - Store in a cool dry place. Pesticide Disposal - Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, expressed or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

APEX®, DIACON II®, STRIKE®, and DIANEX®, are registered trademarks of Wellmark International.

Wellmark International Schaumburg IL 60173

Made in USA

For information or in case of an emergency, call 1-800-XXX-XXXX. Visit our Web site: [web site address]

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete.

White - EPA File Copy (original). . Vallow - Applicant copy

Reviewed By: D. Hudson

[Optional text]

RF-9811 EC

Alternate Brand Names: DIACON® II; APEX®; STRIKE® Ultra Professional Midge Control; DIANEX® Emulsifiable Concentrate for Tobacco

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth]

An Insect Growth Regulator

[to Control Insect Pests in Tobacco Processing and Storage Facilities]
[to Prevent the Emergence of Adult Sciarid Flies In Mushroom Culture]
[To Control Stored Product Insects in Cereal Grains, Grain Sorghum (Milo), Corn
(except Sweet Corn and Popcorn), Birdseed, and Peanuts]
[to Prevent the Emergence of Adult Filter Flies and Non-biting Midges in Waste
Water Treatment Facilities]

ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6)	33.6%
OTHER INGREDIENTS*:	66.4%
Total:	100.0%

^{*}Contains petroleum distillates

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements

EPA Reg. No. 2724-427	EPA Est, No.
NET CONTENTS:	• •
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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

	FIRST AID
If in eyes	Hold eye open and rinse slowly and gently with water for 15-20 minutes.
	Remove contact lenses, if present, after the first
	5 minutes, then continue rinsing eyes.
	Call a poison control center or doctor for treatment advice.
lf on skin	Take off contaminated clothing.
	Rinse skin immediately with plenty of water for 15-20 minutes.
	Call a poison control center or doctor for treatment advice.
If swallowed	 Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give ANY liquid to the person. Do not give anything by mouth to an
	unconscious person.
Have the produ	uct container or label with you when calling a poison control
center or docto	or, or going for treatment. You may also contact [phone
number] for en	nergency medical treatment information.
NOTE TO PHY	/SICIAN: Contains petroleum distillate – vomiting may cause

(Include WPS for APEX Mushroom Use pattern)

Personal Protective Equipment (PPE):

aspiration pneumonia.

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber (≥ 14 mils), barrier laminate, or such as 14 mils). viton (≥ 14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.]

[Engineering Controls Statements:

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements mex-bereduced or modified as specified in the WPS.)

[IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.]

[User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.]

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of rinsate or equipment washwaters.

[Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.]

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[AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber
 (≥ 14 mils), barrier laminate, or viton (≥ 14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.]

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(Directions for Use for RF-9811 EC [DIANEX]-Stored Tobacco Products) **INTRODUCTION**: RF-9811 EC is an emulsifiable formulation of the insect growth regulator, (S)-methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead, it interferes with the normal processes of insect development and prevents adult emergence. RF-9811 EC, when used according to label directions, controls the following insects:

Almond moth (Ephestia cautella)

Cigarette beetle (Lasioderma serricorne)

Sawtooth grain beetle (Oryzaephilus surinamensis)

Red flour beetle (Tribolium castaneum)

Tobacco moth (Ephestia elutella)

Indian meal moth (Plodia interpunctella)

Lesser grain borer (Rhyzopertha dominica)

Merchant grain beetle (Oryzaephilus mercator)

Confused flour beetle (*Tribolium confusum*)

Warehouse beetle (Trogoderma spp.)

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply RF-9811 EC as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply RF-9811 EC at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of RF-9811 EC to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions : Partially fill the mixing container with wa mix and complete filling with quantity of water specified above.	Use diluted spra	⊏(•, iV • •
solution within 24 hours of mixing. Agitate before each use.	. Goo anatoa opia	•••••
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(Directions for Use for DIACON -Stored Product Insects)

PRODUCT INFORMATION: (S)-methoprene, the active ingredient in DIACON[®], protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, DIACON is not an adulticide, but its residual activity prevents the development of larvae into adults. DIACON, when used according to the label directions, prevents regeneration of the following insects: almond moth, Indian meal moth, cigarette beetle, lesser grain borer, sawtooth grain beetle, merchant grain beetle, red flour beetle, and confused flour beetle. Treat existing insect populations with an adulticide before applying DIACON for residual protection.

If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain-damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

Stored Grain: For protection of stored food, feed, oil and seed grains against stored grain insects - for optimum results, thoroughly clean and treat grain storage areas prior to storage of grain. DIACON may also be applied as a top-dressing to stored products that have already been placed into bins or storage areas. Use the rate of 2.5 - 5 ppm for this type of application. Do not flood top-dress area.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED: Dilute DIACON with water or FDA-approved food grade oils* or soybean oil and apply to the moving grain stream as a coarse spray to give a deposit of 5 ppm of DIACON on the grain. Use a final water solution volume of 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. Apply final spray volumes of oil solutions at the oil manufacturer's label application rates. Agitation of water or oil solutions is necessary.

For maximum residual and efficacy, use the rate of 5 ppm. For shorter term residual, lower rates may apply, but do not use rates less than 1 ppm.

DIACON is to be applied in solution in accordance with the general directions to stored products at the following rates per 1000 bushels to provide treatment with 5 ppm concentrations of DIACON. When using lower rates, use the appropriate amount of formulation to achieve the desired application rate:

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	<u>5 p</u>	<u>5 ppm</u>		2.5 ppm		1 ppm	
	fl oz	<u>ml</u>	fl oz	<u>ml</u>	fl oz	ml	
Wheat	7.70	228	4.0	114	1.54	46	
Corn	7.10	212	3.5	106	1.42	43	
Grain sorghum (Milo)	7.10	212	3.5	106	1.42	43	
Barley	6.10	182	3.0	91	1.22	37	
Rice	5.70	170	3.0	85	1.10	34	
Oats	4.10	121	2.0	61	0.80	25	
Peanuts*	3.85	115	2.0	60	0.80	24	

^{*}For peanuts, use water solution only

USE PRECAUTIONS:

- Apply DIACON grain protectant only to grain of known treatment history, apply no more than once per crop.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of DIACON to a spray tank partially filled with water or mineral oil, mix and complete filling with specified quantity of carrier.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.
- Do not treat at extremely dusty sites.

DIACON may also be used as a fogging concentrate or surface spray for the treatment of warehouses, silos, storage bins or other stored commodity areas. For application of DIACON as a fogging or space spray, use the following directions.

Application with Cold Aerosol Generators: Apply DIACON as a mist or aerosol. Dilute with water or oil as required following the instructions of the spray equipment manufacturer. Apply DIACON at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of DIACON to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add DIACON, mix and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

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(Directions for Use for APEX – Mushrooms)
(S)-methoprene, the active ingredient in APEX® insect growth regulator (IGR) is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of (S)-methoprene does not result in immediate insect kill, it interferes with the normal process of insect development. APEX will prevent the emergence of adult sciarid flies when incorporated into the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adults present at the time of application will not be affected. If high adult populations are present initially, use of a conventional adulticide will ensure the best overall results. After treatment with APEX, larvae will continue to develop to the pupal stage where they will die. Estimation of adult fly populations should be no earlier than 2 weeks after treatment to assess the full benefit of APEX.

METHOD, RATE, AND TIMING OF APPLICATION: For best results, incorporate APEX in the mushroom growing medium.

Follow either **METHOD A, METHOD B, or METHOD C** Application Instructions.

A. INCORPORATE IN CASING AT TIME OF CASING

Apply APEX at the rate of 5½ fluid ounces per 1000 sq ft (fl oz/1000 sq ft). Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after placement.

B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

In Compost: Apply APEX at the rate of 5½ fl oz/1000 sq ft in adequate water for even distribution. Spray or sprinkle on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

In Casing: Apply APEX at the rate of 2½ fl oz/1000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a 16-day or longer spawn run, a split application can be used.

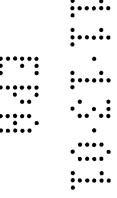
First Application, on compost: Apply APEX 12-13 days after spawning. Drench APEX evenly on the surface at the rate of 2¾ fl oz/1000 sq ft in adequate water for even distribution.

Second Application, in casing: Apply APEX at the rate of 2¾ fl oz/1000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

- 1. Add the measured amount of APEX to a spray tank partially filled with water, mix, and complete filling with specified quantity of water.
- 2. Use diluted spray solution within 48 hours of mixing. Agitate before each use.

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EFFECT ON MUSHROOMSIn most cases, treatment with APEX has a beneficial effect on mushroom yield through control of damaging sciarid fly larvae. The user can determine if reduced crop yields will occur under his own cultural conditions by conducting test treatments on small plots.



Directions for Use for non-biting midges/filter flies

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

MIXING AND HANDLING INSTRUCTIONS:

Partially fill spray container with water; then add the specified amount of RF-9811 EC, agitate, and complete filling. Agitate mildly during application. Agitation can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

USE APPLICATIONS

Waste Water Treatment Facility Pests: Use RF-9811 EC in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

What to Expect in Waste Water Treatment Facilities Continuous Flow Sewage (waste water)

In order to achieve effective results, RF-9811 EC must be applied daily for at least 2 weeks. If applications are not made on a continuous basis, erratic results may occur. Following initial applications of RF-9811 EC, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be very noticeable within a 2 week period following continuous application. Due to varying conditions or heavy infestations, a longer period may be necessary for control. Since the mode of action of RF-9811 EC is to prevent adult emergence, existing adults and pupae present at the time of initial application will complete their life cycle.

As adult suppression peaks, use a maintenance rate of RF-9811 EC for continuous protection from population rebound. However, if application of RF-9811 EC is halted following population suppression, rebound of the population can be expected within 2 to 3 weeks after stopping application. For continuous suppression throughout the pest season, continue applications of RF-9811 EC.

Sludge or Solid Waste Applications

For solid waste applications, use the initial high rate. Apply dilution until the drying beds have been filled. Following filling of the drying beds, halt the dilution application. Make applications of the dilution at the <u>influent</u> side as the sludge or solids enter into the drying beds. Application of RF-9811 EC to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.

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METHODS OF APPLICATION

Waste Water Treatment Facilities: Dilute RF-9811 EC with water prior to use. Apply RF-9811 EC by using a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence appropriate product dilution. Depending on the dosage rate, prepare desired volume of dilution to apply over a 24 hour period (day tank), or in cases of sludge beds, applied until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of RF-9811 EC over a 24 hour period. Mix sufficient material in advance to provide for applications longer than 24 hours. Metering pumps that are capable of delivering material for more than 24 hours will provide best results.

APPLICATION RATE

Waste Water Treatment Pests:

Initial Application - 2.5 to 3.0 ounces of RF-9811 EC per 1 million gallons of sewage (waste water) in sufficient water to apply uniformly at the influent side over a 24 hour period.

Maintenance Rate - 1.5 to 2.0 ounces RF-9811 EC per 1 million gallons of sewage (waste water) in sufficient water to apply uniformly at the influent side over a 24 hour period.

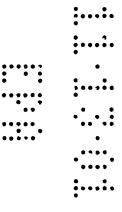
To achieve effective results, use initial application rates on a daily basis for 2 weeks, without interruption. Use sufficient water/RF-9811 EC to achieve uniform application to sewage (waste water) over a 24 hour period. Make application of the dilution at the <u>influent</u> side of the particular area to be treated.]

Maintain initial rate of application for 2 weeks and then for continued effectiveness, follow the directions for the maintenance rate.

APPLICATION SITES

Waste Water Treatment Facilities: Make applications of RF-9811 EC to sewage as it <u>flows into</u> trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem.

Make RF-9811 EC applications as the sewage enters (influent areas) the targeted processing area. Failure to add the material at the influent side may result in erratic results.



STORAGE and DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Storage - Store in a cool dry place. Pesticide Disposal - Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

WARRANTY AND CONDITIONS OF SALE

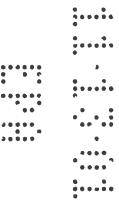
Seller makes no warranty, expressed or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

APEX®, DIACON II®, STRIKE®, and DIANEX®, are registered trademarks of Wellmark International.

Wellmark International Schaumburg IL 60173

Made in USA

For information or in case of an emergency, call 1-800-XXX-XXXX. Visit our Web site: [web site address]





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November 8, 2001

Document Processing Desk (NOTIF) Office of Pesticide Programs 7504C U.S. Environmental Protection Agency Room 266A Crystal Mall 2 1921 Jefferson Davis Highway Arlington, Virginia 22202

ATTENTION: S. Reilly

SUBJECT:

NOTIFICATION OF ALTERNATE BRAND NAMES PER PRN 98-10

RF 9811 EC/EPA REG. NO. 2724-427

Dear Ms. Reilly:

Enclosed is a completed EPA Form 8570-1 and 1 copy of revised highlighted labeling to serve as notification of the following alternate brand names for the above registration:

° [∤]CDIACON® II

○⊭RIZACON™

OK APEX®

∩ | STRIKE® Ultra Professional Midge Control

DIANEX® Emulsifiable Concentrate for Tobacco Following in Kypt. under 2724-427]

I've enclosed a stamped, self-addressed postcard to confirm notification acceptance. If you have any questions, please, call me directly at 847/330-5376. Thank you for your assistance in this matter.

Yours sincerely,

WELLMARK INTERNATIONAL

Mancy Shell

Nancy Huebl

Regulatory Specialist

enclosure

CC:

C. Elmi/J. Richardson



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV - 2 2001

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Steven R. Spaulding Wellmark International 1100 E. Woodfield Road Schaumburg, IL 60173

Dear Mr. Spaulding:

Subject:

Formulation Amendment Application and Confidential Statement of Formula

Your Submission Dated September 19, 2000 EPA Registration No. 2724-427, RF-9811EC

On the basis of information furnished by the registrant, the above named pesticide is hereby amended under the Federal Insecticide, Fungicide and Rodenticide Act. This action does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect this registration, the Agency will require submission of such data under section 3(c)(2)(B).

This amended registration allows for the inclusion of new uses (mushrooms, stored grains, corn, birdseed and peanuts, and waste water treatment facilities) to the label. This amendment also changes the emulsifier/solvent system by removing a potential eye irritant.

The Confidential Statement of Formula submitted for the new formulation (amendment) cited above is acceptable and has been place in the file. In addition, a stamped copy of your new label is enclosed.

Sincerely,

Sheryl K. Reilly, Ph.D. Chief

Biochemical Pesticides Branch

Biopesticides and Pollution

Prevention Division (7511C)

Enclosures

[Optional text]

RF-9811 EC

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth]

An Insect Growth Regulator

[to Control Insect Pests in Tobacco Processing and Storage Facilities]
[to Prevent the Emergence of Adult Sciarid Flies In Mushroom Culture]
[To Control Stored Product Insects in Cereal Grains, Grain Sorghum (Milo), Corn (except Sweet Corn and Popcorn), Birdseed, and Peanuts]

[to Prevent the Emergence of Adult Filter Flies and Non-biting Midges in Waste Water Treatment Facilities]

ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6)	33.6%
OTHER INGREDIENTS*:	66.4%
Total:	100.0%

^{*}Contains petroleum distillates

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements

EPA Reg. No. 2724-427

NET CONTENTS:

NOV - 2 2001

Under the Federal Insecticides.
Fungicide, and Redenticide Act.
on commission for the positicide
registered under 2724-427

EPA Est. No.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

	FIRST AID
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or doctor for treatment advice.
lf on skin	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
If swallowed	Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give ANY liquid to the person. Do not give anything by mouth to an unconscious person.
Have the prod	uct container or label with you when calling a poison control
number] for en	or, or going for treatment. You may also contact [phone nergency medical treatment information.
NOTE TO PH' aspiration pne	YSICIAN: Contains petroleum distillate – vomiting may cause umonia.

(Include WPS for APEX Mushroom Use pattern)

Personal Protective Equipment (PPE):

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber (≥ 14 mils), barrier laminate, or viton (≥ 14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.]

[Engineering Controls Statements:

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.]

[IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.]

[User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.]

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of rinsate or equipment washwaters.

[Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.]

[AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber
 (≥ 14 mils), barrier laminate, or viton (≥ 14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.]

(Directions for Use for RF-9811 EC [DIANEX]-Stored Tobacco Products) **INTRODUCTION**: RF-9811 EC is an emulsifiable formulation of the insect growth regulator, (S)-methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead, it interferes with the normal processes of insect development and prevents adult emergence. RF-9811 EC, when used according to label directions, controls the following insects:

Almond moth (Ephestia cautella)

Cigarette beetle (Lasioderma serricorne)

Sawtooth grain beetle (Oryzaephilus surinamensis)

Red flour beetle (Tribolium castaneum)

Tobacco moth (Ephestia elutella)

Indian meal moth (Plodia interpunctella)

Lesser grain borer (Rhyzopertha dominica)

Merchant grain beetle (Oryzaephilus mercator)

Confused flour beetle (Tribolium confusum)

Warehouse beetle (Trogoderma spp.)

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply RF-9811 EC as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply RF-9811 EC at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of RF-9811 EC to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add RF-9811 EC, mix and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

(Directions for Use for DIACON -Stored Product Insects)

PRODUCT INFORMATION: (S)-methoprene, the active ingredient in DIACON®, protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, DIACON is not an adulticide, but its residual activity prevents the development of larvae into adults. DIACON, when used according to the label directions, prevents regeneration of the following insects: almond moth, Indian meal moth, cigarette beetle, lesser grain borer, sawtooth grain beetle, merchant grain beetle, red flour beetle, and confused flour beetle. Treat existing insect populations with an adulticide before applying DIACON for residual protection.

If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain-damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

Stored Grain: For protection of stored food, feed, oil and seed grains against stored grain insects - for optimum results, thoroughly clean and treat grain storage areas prior to storage of grain. DIACON may also be applied as a top-dressing to stored products that have already been placed into bins or storage areas. Use the rate of 2.5 - 5 ppm for this type of application. Do not flood top-dress area.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED: Dilute DIACON with water or FDA-approved food grade oils* or soybean oil and apply to the moving grain stream as a coarse spray to give a deposit of 5 ppm of DIACON on the grain. Use a final water solution volume of 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. Apply final spray volumes of oil solutions at the oil manufacturer's label application rates. Agitation of water or oil solutions is necessary.

For maximum residual and efficacy, use the rate of 5 ppm. For shorter term residual, lower rates may apply, but do not use rates less than 1 ppm.

DIACON is to be applied in solution in accordance with the general directions to stored products at the following rates per 1000 bushels to provide treatment with 5 ppm concentrations of DIACON. When using lower rates, use the appropriate amount of formulation to achieve the desired application rate:

	5 ppm		2.5 ppm		1 ppm	
	<u>fl oz</u>	<u>ml</u>	<u>fl oz</u>	<u>ml</u>	<u>fl oz</u>	<u>ml</u>
Wheat	7.70	228	4.0	114	1.54	46
Corn	7.10	212	3.5	106	1.42	43
Grain sorghum (Milo)	7.10	212	3.5	106	1.42	43
Barley	6.10	182	3.0	91	1.22	37
Rice	5.70	170	3.0	85	1.10	34
Oats	4.10	121	2.0	61	0.80	25
Peanuts*	3.85	115	2:0	60	0.80	24

^{*}For peanuts, use water solution only

USE PRECAUTIONS:

- Apply DIACON grain protectant only to grain of known treatment history, apply no more than once per crop.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of DIACON to a spray tank partially filled with water or mineral oil, mix and complete filling with specified quantity of carrier.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.
- Do not treat at extremely dusty sites.

DIACON may also be used as a fogging concentrate or surface spray for the treatment of warehouses, silos, storage bins or other stored commodity areas. For application of DIACON as a fogging or space spray, use the following directions.

Application with Cold Aerosol Generators: Apply DIACON as a mist or aerosol. Dilute with water or oil as required following the instructions of the spray equipment manufacturer. Apply DIACON at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of DIACON to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add DIACON, mix and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

(Directions for Use for APEX – Mushrooms) (S)-methoprene, the active ingredient in APEX® insect growth regulator (IGR) is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of (S)-methoprene does not result in immediate insect kill, it interferes with the normal process of insect development. APEX will prevent the emergence of adult sciarid flies when incorporated into the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adults present at the time of application will not be affected. If high adult populations are present initially, use of a conventional adulticide will ensure the best overall results. After treatment with APEX, larvae will continue to develop to the pupal stage where they will die. Estimation of adult fly populations should be no earlier than 2 weeks after treatment to assess the full benefit of APEX.

METHOD, RATE, AND TIMING OF APPLICATION: For best results, incorporate APEX in the mushroom growing medium.

Follow either METHOD A, METHOD B, or METHOD C Application Instructions.

A. INCORPORATE IN CASING AT TIME OF CASING

Apply APEX at the rate of 5½ fluid ounces per 1000 sq ft (fl oz/1000 sq ft). Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after placement.

B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

In Compost: Apply APEX at the rate of 5½ fl oz/1000 sq ft in adequate water for even distribution. Spray or sprinkle on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

In Casing: Apply APEX at the rate of 2½ fl oz/1000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a 16-day or longer spawn run, a split application can be used.

First Application, on compost: Apply APEX 12-13 days after spawning. Drench APEX evenly on the surface at the rate of 2¾ fl oz/1000 sq ft in adequate water for even distribution.

Second Application, in casing: Apply APEX at the rate of 2¾ fl oz/1000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

MIXING AND HANDLING INSTRUCTIONS

- 1. Add the measured amount of APEX to a spray tank partially filled with water, mix, and complete filling with specified quantity of water.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.

EFFECT ON MUSHROOMSIn most cases, treatment with APEX has a beneficial effect on mushroom yield through control of damaging sciarid fly larvae. The user can determine if reduced crop yields will occur under his own cultural conditions by conducting test treatments on small plots.

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

MIXING AND HANDLING INSTRUCTIONS:

Partially fill spray container with water; then add the specified amount of RF-9811 EC, agitate, and complete filling. Agitate mildly during application. Agitation can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

USE APPLICATIONS

Waste Water Treatment Facility Pests: Use RF-9811 EC in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where non-biting midges, filter flies, and other nuisance aquatic insect pests are a problem.

What to Expect in Waste Water Treatment Facilities Continuous Flow Sewage (waste water)

In order to achieve effective results, RF-9811 EC must be applied daily for at least 2 weeks. If applications are not made on a continuous basis, erratic results may occur. Following initial applications of RF-9811 EC, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be very noticeable within a 2 week period following continuous application. Due to varying conditions or heavy infestations, a longer period may be necessary for control. Since the mode of action of RF-9811 EC is to prevent adult emergence, existing adults and pupa present at the time of initial application will complete their life cycle.

As adult suppression peaks, use a maintenance rate of RF-9811 EC for continuous protection from population rebound. However, if application of RF-9811 EC is halted following population suppression, rebound of the population can be expected within 2 to 3 weeks after stopping application. For continuous suppression throughout the pest season, continue applications of RF-9811 EC

Sludge or Solid Waste Applications

For solid waste applications, use the initial high rate. Apply dilution until the drying beds have been filled. Following filling of the drying beds, halt the dilution application. Make applications of the dilution at the <u>influent</u> side as the sludge or solids enter into the drying beds. Application of RF-9811 EC to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.

METHODS OF APPLICATION

Waste Water Treatment Facilities: Dilute RF-9811 EC with water prior to use. Apply RF-9811 EC by using a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence appropriate product dilution. Depending on the dosage rate, prepare desired volume of dilution to apply over a 24 hour period (day tank), or in cases of sludge beds, applied until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of RF-9811 EC over a 24 hour period. Mix sufficient material in advance to provide for applications longer than 24 hours. Metering pumps that are capable of delivering material for more than 24 hours will provide best results.

APPLICATION RATE

Waste Water Treatment Pests:

Initial Application - 2.5 to 3.0 ounces of RF-9811 EC per 1 million gallons of sewage (waste water) in sufficient water to apply uniformly at the influent side over a 24 hour period.

Maintenance Rate - 1.5 to 2.0 ounces RF-9811 EC per 1 million gallons of sewage waste water in sufficient water to apply uniformly at the influent side over a 24 hour period.

To achieve effective results, use initial application rates on a daily basis for 2 weeks, without interruption. Use sufficient water/RF-9811 EC to achieve uniform application to sewage (waste water) over a 24 hour period. Make application of the dilution at the <u>influent</u> side of the particular area to be treated.]

Maintain initial rate of application for 2 weeks and then for continued effectiveness, follow the directions for the maintenance rate.

APPLICATION SITES

Waste Water Treatment Facilities: Make applications of RF-9811 EC to sewage as it <u>flows into</u> trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem.

Make RF-9811 EC applications as the sewage enters (influent areas) the targeted processing area. Failure to add the material at the influent side may result in erratic results.

STORAGE and DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. **Storage** - Store in a cool dry place. **Pesticide Disposal** - Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal** - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

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Wellmark International Schaumburg IL 60173

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For information or in case of an emergency, call 1-800-XXX-XXXX. Visit our Web site: [web site address]



October 25, 2001

Mr. James Downing Office of Pesticide Programs (H7504C) U.S. Environmental Protection Agency Room 910, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA. 22202

SUBJECT: Response to EPA Science Review in Support of a Label and Formulation

Amendment for RF-9811 EC (Zoecon RF-342 Emulsifiable Concentrate -

EPA Reg. No. 2724-427)

Dear Jim:

Per our telephone conversation this morning, I am including a revised Confidential Statement of Formula (CSF) and comments related to the conclusions and recommendations from the above-referenced science review dated October 23, 2001.

- 1a.) A 14-Month Interim Storage Stability and Package Compatibility Study on RF-9811 EC (Study #2684) has been completed and will be submitted by separate correspondence directly to the Document Processing Desk. As stated in the science review, the study will be completed in 9/2002 at which time we will submit the final report to the Agency.
- 1b.) We did not provide a discussion of the formation of impurities since we believe this requirement relates only to the active ingredient and not the formulation which is the subject of this amendment. However, Wellmark formulation chemists provided me with the following brief discussion of the formulation of impurities to include with this letter:

The product is produced in a formulation process and not as an integrated system. No known additional impurities are formed during the formulation process that are not already in the technical grade of active ingredient, (S)-methoprene. This active ingredient, being an unsaturated sesquiterenoid diene conjugated with carboxylate ester is susceptible to both free-radical oxidative degradation and UV induced photolysis.

2.) A revised CSF is included with this letter designating the correct CAS # for has been removed from the Supplier Column on the CSF.

5.) We have verified that all inert ingredients in RF-9811 EC are cleared for food use in subparagraph (c) of 40 CFR 180.1001 and are identified in that section as follows:

Trade/Common Name and (CAS Number) as designated on the CSF 40 CFR Subpart D Subparagraph Section 180.1001 Subparagraph (c) Designation



- 6.) Product performance studies were not submitted for midges since we do not believe that midges found in wastewater treatment facilities are vectors for disease transmission and therefore are not considered public health pests.
- 7.) In the cover letter for this amendment dated September 18, 2000, we requested in point 4 that the primary brand name be changed from Zoecon RF-342 Emulsifiable Concentrate to RF-9811 EC in order to avoid future confusion about these different formulations. The label submitted with the September 2000 amendment indicated the product name as RF9811 EC; however, the product name on the CSF was designated Zoecon RF-342 Emulsifiable Concentrate (RF9811-EC). In order to avoid confusion, the product name on the revised CSF included with this letter has been revised to RF-9811 EC which is now consistent with the product label. Please take steps to initiate the change in the primary brand name of this product within EPA databases to RF-9811 EC.

The science review also indicated that the phrase "in POTW Facilities" must be added after "Filter Flies" and the word "Midges" must be removed. The efficacy study submitted with the amendment was conducted in three Public Owned Treatment Works (POTW) in Kansas. These facilities are examples of the broader category of "Wastewater

Treatment Sites" included on the master label and therefore we do not believe that we should be restricted to the more specific site just because the efficacy study included with the amendment was conducted in POTW's. In addition, we do not believe that midges should be removed from the label because they are not public health pests in wastewater treatment sites.

Please contact me at (847) 330-5380 if you have any questions.

Sincerely yours,

Sk Scauld
Steven R. Spaulding

Manager, Regulatory Affairs

Wellmark

September 28, 2001

Mr. James Downing
Office of Pesticide Programs 7504C
U.S. Environmental Protection Agency
Room 910 Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

SUBJECT:

CLEAN LABELS FOR EPA STAMPED APPROVAL FOR

ZOECON® RF-342 (RF9811) EMULSIFIABLE CONCENTRATE

EPA REG. NO. 2724-427

Dear Jim:

Per your phone conversation with Steve Spaulding this afternoon, I've enclosed 5 clean copies of the above label including your requested suggestions. A copy of this label will be stamped approved and returned to Wellmark for state registration purposes. Sorry, the email version didn't work out. Thanks for all your help to finalize this project. If you need anything further, give me (847) 330-5376 or Steve (847) 330-5380 a call.

Yours sincerely,

WELLMARK INTERNATIONAL

Mancy Hueld

Nancy Huebl

Regulatory Specialist

Enclosure

cc: S. Spaulding

Label Review Sheet

FILENAME:

PRODUCT:

g:\regulatory\LABELS\

CAHSPEC\02724427\

COVERSHEET UPDATE:

September 2000

pz342ECA 00A

ZOECON RF-342

(RF9811) EMULSIFIABLE

EPA REG. NO.:

2724-427

CONCENTRATE

APPROVED:

Amendment submitted 9/00

SUPERSEDES:

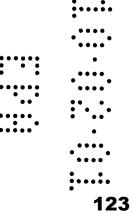
OVERVIEW: Transfer use patterns (mushrooms/APEX – 2724-452 and stored grains/Altosid 5E-FZ-515/DIACON – 2724-477) from R/S methoprene formulation to S-methoprene formulation; Add new pests – filter flies and midges (registered as pests under Zoecon RF437 Mosquito Growth Regulator, 2724-446 - 20% S-methoprene)

Change primary brand name from Zoecon RF-342 Emulsifiable Concentrate for Tobacco to RF-9811 EC (DIANEX)

Red text represents revisions to RF 342 EC (now RF-9811EC), <u>added text in other colored areas (DFU's) is underlined</u>, any text to be deleted is marked as strikethrough

Page #	Description of Major Changes					
1	Header revised to reflect change in primary brand name (see above overview) include pests/sites from APEX/DIACON labels, new pests/sites added (filter flies/midges)					
	Ingredient Statement: Chemical name dropped, added CAS # - PRN 97-5					
	"Inert" changed to "Other" – PRN 97-6					
	Added asterisk following "Other Ingredients" to indicate that formulation contains petroleum distillates					
2-3	Precautionary Statements – Updated per 12/96 Label Review Manual, tox data submitted, included WPS language from APEX label					
	First Aid statements added per PRN 2000-3					
	Optional Worker Protection Standard language added to reflect APEX mushroom use pattern, revised based on changed formulation – new chemical resistance category (F to E), revised types of chemical-resistant gloves, added Engineering Controls section, added User Safety Recommendations box					
	Environmental Hazards – added optional text relevant to filter fly/midge aquatic use only					
	Physical/Chemical Hazard statement removed based on new formulation's flashpoint					
4	Optional WPS Ag Use box added/revised PPE based on formulation change (for APEX/mushroom use)					
	Added optional "Do not apply irrigation system" (for APEX label)					

5	Directions for Use/DIANEX – First paragraph, added "S" to methoprene
	revised name to reflect new formulation
6	Added DFU from DIACON label with revisions as follows: Methoprene revised to S-methoprene, "5E" removed from product name First paragraph/last sentence – "fumigated" changed to "treated" – clarity
	Second Paragraph – added " <u>1 kg</u> sample…", clarity, added FGIS reference statement.
	Stored Grain: Additional application method – top dressing for already stored products
	General Directions/Rate table: added shorter residue, lower rates
7	Additional DIACON DFU revisions: Dilution chart, added lower rates (2ppm, 1ppm) dilution figures
	Directions (same as DIANEX DFU) for fogging, space spray added for DIACON
8-9	Added DFU from APEX label – removed "5E" from name
10-11	Added DFU for filter flies/midges – waste water treatment facilities
12	Added trademark reference Information reference – added "or in case of an emergency" (stewardship) Added web site statement



[Optional text]

RF-9811 EC

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth]

An Insect Growth Regulator for the Control of [Insect Pests in Tobacco Processing and Storage Facilities] [to Prevent the Emergence of Adult Sciarid Flies In Mushroom Culture] [Stored Product Insects in Cereal Grains, Grain Sorghum (Milo), Corn (except

Sweet Corn and Popcorn), Birdseed, and Peanuts [to Prevent the Emergence of Adult Filter Flies and Midges] in Waste Water Treatment Facilities Mon- biting

ACTIVE INGREDIENT:

(S)-Methoprene (CAS #65733-16-6)	33.6%
OTHER INGREDIENTS*:	66.4%
Total:	100.0%

^{*}Contains petroleum distillates

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements

EPA Reg. No. 2724-427

EPA Est. No.

NET CONTENTS:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if absorbed through skin. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

	FIRST AID				
If in eyes	Hold eye open and rinse slowly and gently				
:	with water for 15-20 minutes.				
	Remove contact lenses, if present, after the				
	first 5 minutes, then continue rinsing eyes.				
	Call a poison control center or doctor for				
	treatment advice.				
lf on skin	Take off contaminated clothing.				
	Rinse skin immediately with plenty of water for 15-20				
	minutes.				
	Call a poison control center or doctor for				
	treatment advice.				
If swallowed	Immediately call a poison control center or doctor.				
	Do not induce vomiting unless told to do so by a				
	poison control center or doctor. Do not give ANY				
	liquid to the person. Do not give anything by mouth				
	to an unconscious person.				
Have the produ	uct container or label with you when calling a poison control				
center or docto	or, or going for treatment. You may also contact [phone				
number] for en	nergency medical treatment information.				
	/SICIAN: Contains petroleum distillate – vomiting may cause				
aspiration pnet	umonia.				

(Include WPS for APEX Mushroom Use pattern)
[Personal Protective Equipment (PPE):

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber (≥ 14 mils), barrier laminate, or viton (≥ 14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.]

[Engineering Controls Statements:

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.1

[IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.]

[User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of rinsate or equipment washwaters.

[Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.]

[AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as neoprene rubber (≥ 14 mils), nitrile rubber
 (≥ 14 mils), barrier laminate, or viton (≥ 14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system.]

(Directions for Use for RF-9811 EC [DIANEX]-Stored Tobacco Products) **INTRODUCTION**: RF-9811 EC is an emulsifiable formulation of the insect growth regulator, (S)-methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead, it interferes with the normal processes of insect development and prevents adult emergence. RF-9811 EC, when used according to label directions, controls the following insects:

Almond moth (Ephestia cautella)

Cigarette beetle (Lasioderma serricorne)

Sawtooth grain beetle (Oryzaephilus surinamensis)

Red flour beetle (*Tribolium castaneum*)

Tobacco moth (Ephestia elutella)

Indian meal moth (Plodia interpunctella)

Lesser grain borer (Rhyzopertha dominica)

Merchant grain beetle (Oryzaephilus mercator)

Confused flour beetle (Tribolium confusum)

Warehouse beetle (*Trogoderma* spp.)

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply RF-9811 EC as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply RF-9811 EC at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of RF-9811 EC to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add RF-9811 EC, mix and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

(Directions for Use for DIACON -Stored Product Insects)

PRODUCT INFORMATION: (S)-methoprene, the active ingredient in DIACON[®], protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, DIACON is not an adulticide, but its residual activity prevents the development of larvae into adults. DIACON, when used according to the label directions, prevents regeneration of the following insects: almond moth, Indian meal moth, cigarette beetle, lesser grain borer, sawtooth grain beetle, merchant grain beetle, red flour beetle, and confused flour beetle. Treat existing insect populations with an adulticide before applying DIACON for residual protection.

If stored grain insect populations exceed 2 insects per 1 kg sample during storage, fumigate to avoid grain-damage from existing insects. Refer to Federal Grain Inspection Service regulations for stored grain for more information on sampling and insect thresholds.

Stored Grain: For protection of stored food, feed, oil and seed grains against stored grain insects - for optimum results, thoroughly clean and treat grain storage areas prior to storage of grain. DIACON may also be applied as a top-dressing to stored products that have already been placed into bins or storage areas. Use the rate of 2.5 - 5 ppm for this type of application. Do not flood top-dress area.

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED: Dilute DIACON with water or FDA-approved food grade oils* or soybean oil and apply to the moving grain stream as a coarse spray to give a deposit of 5 ppm of DIACON on the grain. Use a final water solution volume of 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. Apply final spray volumes of oil solutions at the oil manufacturer's label application rates. Agitation of water or oil solutions is necessary.

For maximum residual and efficacy, use the rate of 5 ppm. For shorter term residual, lower rates may apply, but do not use rates less than 1 ppm.

DIACON is to be applied in solution in accordance with the general directions to stored products at the following rates per 1000 bushels to provide treatment with 5 ppm concentrations of DIACON. When using lower rates, use the appropriate amount of formulation to achieve the desired application rate:

	<u>5 ppm</u>		2.5 ppm		1 ppm	
	fl oz	<u>ml</u>	<u>fl oz</u>	<u>ml</u>	<u>fl oz</u>	<u>ml</u>
Wheat	7.70	228	4.0	114	1.54	46
Corn	7.10	212	3.5	106	1.42	43
Grain sorghum (Milo)	7.10	212	3.5	106	1.42	43
Barley	6.10	182	3.0	91	1.22	37
Rice	5.70	170	3.0	85	1.10	34
Oats	4.10	121	2.0	61	0.80	25
Peanuts*	3.85	115	2.0	60	0.80	24

^{*}For peanuts, use water solution only

USE PRECAUTIONS:

- Apply DIACON grain protectant only to grain of known treatment history, apply no more than once per crop.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of DIACON to a spray tank partially filled with water or mineral oil, mix and complete filling with specified quantity of carrier.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.
- Do not treat at extremely dusty sites.

DIACON may also be used as a fogging concentrate or surface spray for the treatment of warehouses, silos, storage bins or other stored commodity areas. For application of DIACON as a fogging or space spray, use the following directions.

Application with Cold Aerosol Generators: Apply DIACON as a mist or aerosol. Dilute with water or oil as required following the instructions of the spray equipment manufacturer. Apply DIACON at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of DIACON to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add DIACON, mix and complete filling with quantity of water specified above. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

(Directions for Use for APEX – Mushrooms)
(S)-methoprene, the active ingredient in APEX® insect growth regulator (IGR) is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of (S)-methoprene does not result in immediate insect kill, it interferes with the normal process of insect development. APEX will prevent the emergence of adult sciarid flies when incorporated into the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adults present at the time of application will not be affected. If high adult populations are present initially, use of a conventional adulticide will ensure the best overall results. After treatment with APEX, larvae will continue to develop to the pupal stage where they will die. Estimation of adult fly populations should be no earlier than 2 weeks after treatment to assess the full benefit of APEX.

METHOD, RATE, AND TIMING OF APPLICATION: For best results, incorporate APEX in the mushroom growing medium.

Follow either **METHOD A, METHOD B, or METHOD C** Application Instructions.

A. INCORPORATE IN CASING AT TIME OF CASING

Apply APEX at the rate of 5½ fluid ounces per 1000 sq ft (fl oz/1000 sq ft). Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after placement.

B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

In Compost: Apply APEX at the rate of 5½ fl oz/1000 sq ft in adequate water for even distribution. Spray or sprinkle on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

In Casing: Apply APEX at the rate of 2½ fl oz/1000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a 16-day or longer spawn run, a split application can be used.

First Application, on compost: Apply APEX 12-13 days after spawning. Drench APEX evenly on the surface at the rate of 2¾ fl oz/1000 sq ft in adequate water for even distribution.

Second Application, in casing: Apply APEX at the rate of 2¾ fl oz/1000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

MIXING AND HANDLING INSTRUCTIONS

- 1. Add the measured amount of APEX to a spray tank partially filled with water, mix, and complete filling with specified quantity of water.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.

EFFECT ON MUSHROOMSIn most cases, treatment with APEX has a beneficial effect on mushroom yield through control of damaging sciarid fly larvae. The user can determine if reduced crop yields will occur under his own cultural conditions by conducting test treatments on small plots.

Directions for Use for midges/filter flies

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

MIXING AND HANDLING INSTRUCTIONS:

Partially fill spray container with water; then add the specified amount of RF-9811 EC, agitate, and complete filling. Agitate mildly during application. Agitation can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

RECOMMENDED APPLICATIONS

Waste Water Treatment Facility Pests: Use RF-9811 EC in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where midges, filter flies, and other nuisance aquatic insect pests are a problem.

What to Expect in Waste Water Treatment Facilities Continuous Flow Sewage (waste water)

In order to achieve effective results, RF-9811 EC must be applied daily for at least 2 weeks. If applications are not made on a continuous basis, erratic results may occur. Following initial applications of RF-9811 EC, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be very noticeable within a 2 week period following continuous application. Due to varying conditions or heavy infestations, a longer period may be necessary for control. Since the mode of action of RF-9811 EC is to prevent adult emergence, existing adults and pupa present at the time of initial application will complete their life cycle.

As adult suppression peaks, use a maintenance rate of RF-9811 EC for continuous protection from population rebound. However, if application of RF-9811 EC is halted following population suppression, rebound of the population can be expected within 2 to 3 weeks after stopping application. For continuous suppression throughout the pest season, continue applications of RF-9811 EC

Sludge or Solid Waste Applications

For solid waste applications, use the initial high rate. Apply dilution until the drying beds have been filled. Following filling of the drying beds, halt the dilution application. Make applications of the dilution at the <u>influent</u> side as the sludge or solids enter into the drying beds. Application of RF-9811 EC to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.

METHODS OF APPLICATION

Waste Water Treatment Facilities: Dilute RF-9811 EC with water prior to use. Apply RF-9811 EC by using a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence appropriate product dilution. Depending on the dosage rate, prepare desired volume of dilution to apply over a 24 hour period (day tank), or in cases of sludge beds, applied until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of RF-9811 EC over a 24 hour period. Mix sufficient material in advance to provide for applications longer than 24 hours. Metering pumps that are capable of delivering material for more than 24 hours will provide best results.

APPLICATION RATE

Waste Water Treatment Pests:

Initial Application - 2.5 to 3.0 ounces of RF-9811 EC per 1 million gallons of sewage (waste water) in sufficient water to apply uniformly at the influent side over a 24 hour period.

Maintenance Rate - 1.5 to 2.0 ounces RF-9811 EC per 1 million gallons of sewage waste water in sufficient water to apply uniformly at the influent side over a 24 hour period.

To achieve effective results, use initial application rates on a daily basis for 2 weeks, without interruption. Use sufficient water/RF-9811 EC to achieve uniform application to sewage (waste water) over a 24 hour period. Make application of the dilution at the <u>influent</u> side of the particular area to be treated.]

Maintain initial rate of application for 2 weeks and then for continued effectiveness, follow the directions for the maintenance rate.

APPLICATION SITES

Waste Water Treatment Facilities: Make applications of RF-9811 EC to sewage as it <u>flows into</u> trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem.

Make RF-9811 EC applications as the sewage enters (influent areas) the targeted processing area. Failure to add the material at the influent side may result in erratic results.

STORAGE and DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. **Storage** - Store in a cool dry place. **Pesticide Disposal** - Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal** - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

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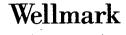
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Wellmark International Schaumburg IL 60173

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Wellmark Interpretational 1100 East Wood, Rood, Suite 500 Schaumburg, Illinois 60173 847 330 5300



September 18, 2000

Document Processing Desk (AMEND) Office of Pesticide Programs (H7504C) U.S. Environmental Protection Agency Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA. 22202

Attn: Dr. Sheryl Reilly

Biopesticides and Pollution Prevention Division

SUBJECT: Zoecon RF-342 Emulsifiable Concentrate – EPA Reg. No. 2724-427 Formulation and Label Amendment

Dear Dr. Reilly:

Please find enclosed an Application for a Formulation and Label Amendment for the above-referenced product. RF-342 Emulsifiable Concentrate (DIANEX) is an Insect Growth Regulator (IGR) containing 33.6% S-Methoprene for the control of insect pests in tobacco processing and storage facilities. The objectives of this amendment application are as follows:

- 1. Change the emulsifier/solvent system in the current RF-342 EC formulation to remove a potential eye irritant.
- 2. Transfer use patterns from two registered R/S-Methoprene formulations to RF-342 Emulsifiable Concentrate containing S-Methoprene. This strategy is consistent with Wellmark plans to phase-out production of R/S-Methoprene. Wellmark submitted an application for formulation amendments to the Agency on February 22, 2000 to convert eight (8) end-use products containing R/S-Methoprene to S-Methoprene. These amendments are based on the rational that the two active ingredients behave essentially the same in end-use, formulations with respect to safety and efficacy.
- 3. Add filter flies and midges as a new pest species to the RF-342 Emulsifiab@Combentrate label.
- 4. Change the primary brand name from Zoecon RF-342 Emulsifiable Concentrate to RF-9811, EC to avoid future confusion.

A brief overview of the products and nomenclature involved in this amendment is as follows:

EPA Product Name	Wellmark Tradename	Research Formula	EPA Reg. No.
Zoecon RF-342 Emulsifiable Concentra	DIANEX	RF-342 (current)	2724-427
RF-9811 EC	DIANEX, APEX, DIACO	N RF-9811 (amended)	2724-427
APEX 5E	APEX	RF-174	2724-452
ALTOSID 5E-FZ-515	DIACON	RF-174	2724-477

RF-342 Emulsifiable Concentrate Formulation Amendment

Wellmark initiated efforts to reformulate RF-342 Emulsifiable Concentrate following indications that this formulation may be a possible eye irritant. A 6(a)(2) Adverse Incident was submitted to the Agency on May 3, 2000 in relation to an eye irritation study conducted with this formulation (MRID #45113701). The emulsifier was suspected as being responsible for the eye irritation and therefore was removed from the formulation and replaced with a reformulated emulsifier system including the new inert ingredient. The new amended Formulation RF-9811 EC reflects the following changes to the emulsifier/solvent system and the changes are outlined in detail in Attachment I:

are new inert ingredients which have been added to the amended basic formulation and these inerts are exempt from the requirements of a tolerance under 40CFR 180.1001c and cleared for food use. The nominal concentration of the active ingredient S-Methoprene remains the same at 33.6%. An ocular irritation study conducted with the amended basic formulation RF9811 EC is included with this submission and showed only mild ocular irritation supporting Tox Category III with a CAUTION signal word which is currently on the approved label.

RF-342 Emulsifiable Concentrate Label Amendment

Wellmark proposes to amend the RF-342 Emulsifiable Concentrate label by transferring use patterns from the following 66.0% R/S-Methoprene registered products to the RF-342 Emulsifiable Concentrate label containing 33.6% S-Methoprene:

- APEX 5E EPA Reg. No. 2724-452 an insect growth regulator to prevent the emergence of adult sciarid flies in mushroom culture.
- DIACON EPA Reg. No. 2724-477 an insect growth regulator for stored product insects in cereal grains, grain sorghum (milo), corn (except sweet corn and popcorn), birdseed and peanuts.

In addition, Wellmark proposes to add filter flies and midges as new pest species to the RF-342 Emulsifiable Concentrate label. These pests have been previously approved on another liquid S-Methoprene formulation (EPA Reg. No. 2724-446).

Three efficacy studies to support all of the above pests and use patterns as well as the biological equivalency of R/S-Methoprene and S-Methoprene are included with this submission. All use patterns have been incorporated into 1 amended master label for RF-342 Emulsifiable Concentrate which will include four different Wellmark products: DIANEX, APEX, DIACON and a Wastewater Treatment Plant product for midges and filter flies.

Product Chemistry

A Self-Certification Summary for the Physical/Chemical Properties of RF-9811 EC, an updated Validated Analytical Method and a Description of Beginning Materials and Manufacturing Procedures specific to RF-9811 EC are included with this submission.

Toxicology

Acute ocular irritation and acute inhalation toxicology studies were repeated with the RF-9811 EC formulation to confirm reduced ocular irritation and to generate confirmatory data to support precautionary label language for a CAUTION signal word as is currently approved on the RF-342 Emulsifiable Concentrate label. Acute oral and dermal toxicity studies and dermal irritation and skin sensitization studies with the similar and current basic formulation of RF-342 Emulsifiable Concentrate are also included as supportive data in this submission. These acute toxicology studies with RF-342 Emulsifiable Concentrate were part of a complete battery of acute studies conducted in 1988 in anticipation that these studies would be required as part of the Phase 5 Reregistration data requirements. However, these studies subsequently were not required by the Agency and therefore not submitted at that time. The original precautionary labeling for RF-342 Emulsifiable Concentrate when the product was first registered in 1989 was based on the acute toxicity of the active ingredients R/S- and S-Methoprene.

A summary of the following acute studies indicates data supportive of Category III / IV precautionary labeling with a CAUTION signal word. There is no reason to believe that RF-9811 EC is more acutely toxic or has greater sensitization potential than RF-342 Emulsifiable Concentrate.

Acute Oral LD50 - >5100 mg/kg - Tox Category IV (RF-342) Acute Dermal LD50 - >2100 mg/kg - Tox Category III (RF-342)

Dermal Irritation - Moderately Irritating - Tox Category III (RF-342)
Eye Irritation - Mildly Irritating - Tox Category III (RF-9811)

Dermal Sensitization - Not a Dermal Sensitizer (RF-342)

Acute Inhalation >2.009 mg/l – Tox Category IV (RF-9811)

Product Performance

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Results from efficacy studies included with this submission and conducted with the new amended RF9811 EC formulation indicated the following:

1. Studies conducted at the University of Guelph, Canada indicated that both the 65:3% R3S- • • Methoprene EC formulation (APEX) and the 33.3% S-Methoprene EC formulation (RE981). DIANEX EC) were effective in preventing the emergence of adult sciarid flies in mushroom cultures.

- 2. Studies conducted by the USDA Grain Marketing and Research Center in Manhattan, Kansas indicated that both the 65.3% R/S-Methoprene EC Formulation (DIACON) and the 33.3% S-Methoprene EC Formulation (DIANEX) was effective in controlling 3 species of stored product pest beetles in wheat for 6 months.
- 3. Studies conducted by Johnson County, Kansas Environmental indicated that the 33.3% S-Methoprene EC formulation (DIANEX) was efficaceous in preventing the emergence of adult filter flies in trickling filter water treatment plants.

The following documentation is being submitted in support of this formulation and label amendment:

- 1. Application for Pesticide Amendment EPA Form 8570-1
- 2. Attachment I Comparative Overview of RF-342 EC Formulation and Label Amendment.
- 3. Confidential Statement of Formula for the Reformulated Basic Formulation (2 copies)
- 4. Master Labels 1 color copy highlighting revisions and 5 clean copies with revisions incorporated.
- 5. Supportive Data Submissions (3 Copies):
 - Volume 1. Wilkins, F.C. (2000). Self-Certification Summary for the Physical/Chemical Properties of RF9811 EC. Report #2700. Wellmark International. Dallas, TX.
 - Volume 2. Thornton, K. (1999). Specificity, Precision and Accuracy of a Chemical Analysis Procedure (CAP) for the Assay of RF9811 EC by Capillary Gas Chromatography. Study #2532. Wellmark International. Dallas, TX.
 - Volume 3. McDaniel, J. (2000). RF9811 EC: Description of Beginning Materials and Manufacturing Procedure. Report # 2533. Wellmark International. Dallas, TX.
 - Volume 4. Michlewicz, K.G. (1988). Acute Oral Toxicity Study of Dianex RF-342 in Rats. SLS Study 3122.6. Springborn Life Sciences. Spencerville, OH.
 - Volume 5. Michlewicz, K.G. (1988). Acute Dermal Toxicity Study of Dianex RF-342 in Rabbits. SLS Study 3122.7. Springborn Life Sciences. Spencerville, OH.
 - Volume 6. Findlay, J. (2000). Acute Eye Irritation Study of RF9811 EC in Rabbits. Study #1313 SN3. ITT Research Institute. Chicago, IL.
 - Volume 7. Michlewicz, K.G. (1988). Primary Skin Irritation Study of Dianex RF-342 in Rabbits. SLS Study 3122.9. Springborn Life Sciences. Spencerville, OH.
 - Volume 8. Michlewicz, K.G. (1988). Delayed Contact Hypersensitivity Study in Guinea Pigs with Dianex RF-342. SLS Study 3122.10. Springborn Life Sciences. Spencerville, OH.
 - Volume 9. Sullivan, D.M. (2000). Acute Nose-Only Inhalation Toxicity Study. Of Liquid Sample RF9811 EC in Rats (Limit Test). Study #1332-001 SN1. ITT Research Institute. Chicago, IL.

Volume 10. Rinker, D. & G. Alm. (2000). Efficacy of Apex Formulations against Mushroom Sciarid Flies. University of Guelph, Ontario, Canada.

Volume 11. Arthur, F. (2000). Residual Efficacy of Two Formulations of Methoprene

to Control Beetles in Stored wheat. USDA Grain Marketing and

Research Center. Manhattan, KS.

Volume 12. Wittek, P. (2000). Effective Filter Fly Control. Johnson County

Environmental. Lenexa, KS.

In conclusion, product chemistry and manufacturing data, acute toxicology studies, product performance studies and an expanded master label incorporating use patterns from registered R/S-Methoprene EC formulations into the registered S-Methoprene EC formulation label are included in this amendment for Zoecon RF-342 Emulsifiable Concentrate. It is our intention to gradually phase-out and eventually cancel all R/S-Methoprene end-use product registrations as inventories of R/S-Methoprene are depleted over the next 2 years. In addition to the label amendment, the formulation was amended as well in order to replace which was suspected as an eye irritant. An ocular irritation study conducted with the RF9811 EC formulation confirmed the lack of eye irritation with the new amended formulation. We also propose to use this as an opportunity to notify the Agency to change the primary brand name from Zoecon RF-342 Emulsifiable Concentrate to RF-9811 EC in order to avoid confusion between these two similar research formulas in the future.

The new amended formulation and label for RF-9811 EC will provide: (1) an improved formulation containing a new non-irritating emulsifier and (2) an expanded master label including tobacco pests (DIANEX), sciarid flies (APEX), stored product pests (DIACON) and filter flies and midges as new dipteran pest species.

Please contact me at (847) 330-5380 if you have any questions.

Sincerely yours,

Steven R. Spaulding

Manager, Regulatory Affairs

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

Wellmark International 1100 East Woodfield Road Suite 5000 Schaumburg, Illinois 60173

REGULATORY ACTION SUPPORTED BY THIS SUBMISSION

Formulation and label amendment for Zoecon RF-342 Emulsifiable Concentrate (EPA Reg. No. 2724-427).

TRANSMITTAL DATE

September 18, 2000

LIST OF SUBMITTED STUDIES

Volume 1. 452144 <i>4)</i>	Wilkins, F.C. (2000). Self-Certification Summary for the Physical/Chemical Properties of RF9811 EC. Report #2700. Wellmark International. Dallas, TX.
Volume 2. 452144ф2	Thornton, K. (2000). Specificity, Precision and Accuracy of a Chemical Analysis Procedure (CAP) for RF9811 EC by Capillary Gas Chromatography. Study #2532. Wellmark International. Dallas, TX.
Volume 3. 452 144 ф3	McDaniel, J. (2000). RF9811 EC: Description of Beginning Materials and Manufacturing Procedure. Report # 2533. Wellmark International. Dallas, TX.
Volume 4. 452144ф4	Michlewicz, K.G. (1988). Acute Oral Toxicity Study of Dianex RF-342 in Rats. SLS Study 3122.6. Springborn Life Sciences. Spencerville, OH.
Volume 5. 452144 <i>45</i>	Michlewicz, K.G. (1988). Acute Dermal Toxicity Study of Dianex RF-342 in Rabbits. SLS Study 3122.7. Springborn Life Sciences. Spencerville, OH.
Volume 6. 452144фЬ	Michlewicz, K.G. (1988). Primary Skin Irritation Study of Dianex RF-342 in Rabbits. SLS Study 3122.9. Springborn Life Sciences. Spencerville, OH.
6(9)は Volume 7. 452144中フ	Findlay, J. (2000). Acute Eye Irritation Study of RF9811 EC in Rabbits. Study #1313 SN3. ITT Research Institute. Chicago, IL.
Volume 8. 452144ф8	Michlewicz, K.G. (1988). Delayed Contact Hypersensitivity Study in Guinea Rigs with Dianex RF-342. SLS Study 3122.10. Springborn Life Sciences. Spencerville, OH.
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Volume 9. Sullivan, D.M. (20

Sullivan, D.M. (2000). Acute Nose-Only Inhalation Toxicity Study

Of Liquid Sample RF9811 EC in Rats (Limit Test). Study #1332-001 SN1. ITT

Research Institute. Chicago, IL.

Volume 10. 45214410

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Rinker, D. & G. Alm. (2000). Efficacy of Apex Formulations against Mushroom

Sciarid Flies. University of Guelph, Ontario, Canada.

Volume 11. 45214411 Arthur, F. (2000). Residual Efficacy of Two Formulations of Methoprene to

Control Beetles in Stored Wheat. USDA Grain Marketing and Research Center.

Manhattan, KS.

Volume 12.

Wittek, P. (2000). Effective Filter Fly Control. Johnson County Environmental.

45214412

Lenexa, KS.

COMPANY NAME:

WELLMARK INTERNATIONAL

COMPANY AGENT:

Steven R. Spaulding

Manager, Regulatory Affairs

Wellmark International 1100 East Woodfield Road Schaumburg, IL. 60173

COMPANY CONTACT:

Steven R. Spaulding

TELEPHONE: (847) 330-5380

SIGNATURE.

DATE: 9-18-00

Please read instructions on re	verse perore completing f	0		Form Approved. Of	WIB NO. 2070-	0060. Approval expires 2-28-95
₩ EPA	Environmen Was	tal Protectio		X Amendm Other		277833
		Applica	ation for Pesticide - Section	n I		
Company/Product Number Wellmark International/272	24-427		EPA Product Manager Reilly		3.1	Proposed Classification
4. Company/Product (Name) Wellmark International/2	Zoecon RF-342 Emulsis	fiable	PM# Biopesticides			X None Restricted
5. Name and Address of Applic Wellmark International 1100 E Woodfield Road Schaumburg IL 60173 Check if this is a		² Code)	6. Expedited Review. (b)(i), my product is si EPA Reg. No Product Name			
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	Applica	tion for Pesticide - Se	ction I	
1. Company/Product Number	or	2. EPA Product M	anager 3.	Proposed Classification
4. Company/Product (Name)	PM#		None Restricted
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1. Material This Product W	ill Be Packaged In:			
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	st	Section - IV		
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Name		Title	Teleph	none No. (Include Area Code)
	Certitements I have made on this form	fication		6. Date Application Received

3. Title

5. Date

2. Signature

4. Typed Name

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send completing regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Stetement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three oopies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION 1 - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you es a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited raview of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter dete if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types.
 Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

ATTACHMENT I Comparative Overview of RF-342 EC / RF-9811 EC Formulation & Label Amendment

Ingredient	Chemical Name	CAS Number	Purpose	DIACON 2724-477 RF-174.001 stored prod. pests	APEX 2724-452 RF174.003 sciarid flies	DIANEX 2724-427 RF-342.002. Current tobacco pests	*RF9811.001 Proposed Amendment plus midges
(R,S)-Methoprene	(94%)	40596-69-8	IGR	71.30% nom= 67%	71.30% nom=67%		
(S)-Methoprene	(94%)	65733-16-6	IGR			35.74% nom=33.6%	35.74% nom=33.6%

Label Review Sheet				
FILENAME:	g:\regulatory\LABELS\ CAHSPEC\02724427\ pz342ECA 00A	COVERSHEET UPDATE:	September 2000	
PRODUCT:	ZOECON RF-342 (RF9811) EMULSIFIABLE CONCENTRATE	EPA REG. NO.:	2724-427	

APPROVED: Amendment submitted 9/00 SUPERSEDES:

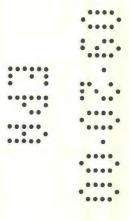
OVERVIEW: Transfer use patterns (mushrooms/APEX – 2724-452 and stored grains/Altosid 5E-FZ-515/DIACON – 2724-477) from R/S methoprene formulation to S-methoprene formulation; Add new pests – filter flies and midges (registered as pests under Zoecon RF437 Mosquito Growth Regulator, 2724-446 - 20% S-methoprene)

Change primary brand name from Zoecon RF-342 Emulsifiable Concentrate for Tobacco to RF-9811 EC (DIANEX)

Red text represents revisions to RF 342 EC (now RF-9811EC), added text in other colored areas (DFU's) is underlined, any text to be deleted is marked as strikethrough

Page #	Description of Major Changes					
1	Header revised to reflect change in primary brand name (see above overview) include pests/sites from APEX/DIACON labels, new pests/sites added (filter flies/midges)					
	Ingredient Statement: Chemical name dropped, added CAS # - PRN 97-5					
	"Inert" changed to "Other" PRN 97-6					
	Added asterisk following "Other Ingredients" to indicate that formulation contains petroleum distillates					
2-3	Precautionary Statements – Updated per 12/96 Label Review Manual, tox data submitted, included WPS language from APEX label					
	First Aid statements added per PRN 2000-3					
	Optional Worker Protection Standard language added to reflect APEX mushroom use pattern, revised based on changed formulation – new chemical resistance category (F to E), revised types of chemical-resistant gloves, added Engineering Controls section, added User Safety Recommendations box					
	Environmental Hazards – added optional text relevant to filter fly/midge aquatic use only					
	Physical/Chemical Hazard statement removed based on new formulation's flashpoint					
4	Optional WPS Ag Use box added/revised PPE based on formulation change (for APEX/mushroom use)					
	Added optional "Do not apply irrigation system" (for APEX label).					

5	Directions for Use/DIANEX - First paragraph, added "S" to methoprene					
	revised name to reflect new formulation					
6	Added DFU from DIACON label with revisions as follows: Methoprene revised to S-methoprene, "5E" removed from product name First paragraph/last sentence – "fumigated" changed to "treated" – clarity					
	Second Paragraph – added <u>"1 kg</u> sample", clarity, added FGIS reference statement.					
	Stored Grain: Additional application method – top dressing for already stored products					
	General Directions/Rate table: added shorter residue, lower rates					
7	Additional DIACON DFU revisions: Dilution chart, added lower rates (2ppm, 1ppm) dilution figures					
	Directions (same as DIANEX DFU) for fogging, space spray added for DIACON					
8-9	Added DFU from APEX label – removed "5E" from name					
10-11	Added DFU for filter flies/midges – waste water treatment facilities					
12	Added trademark reference					
	Address change					
	Information reference – added "or in case of an emergency" (stewardship)					
	Added web site statement					



[Optional text]

ZOECON® RF-342 9811 EC

EMULSIFIABLE CONCENTRATE FOR TOBACCO

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth]

An Insect Growth Regulator for the Control of [Insect Pests in Tobacco Processing and Storage Facilities] Ito Prevent the Emergence of Adult Sciarid Flies In Mushroom Culture [Stored Product Insects in Cereal Grains, Grain Sorghum (Milo), Corn (except

Sweet Corn and Popcorn), Birdseed, and Peanuts1

Ito Prevent the Emergence of Adult Filter Flies and Midges

ACTIVE INGREDIENT:

(S)-Methoprene (Isopropyl (2E, 4E, 7S)-INERT OTHER INGREDIENTS*: 66.4%

*Contains petroleum distillates

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements

EPA Reg. No. 2724-42	1
----------------------	---

EPA Est. No.

NET CONTENTS:

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Causes moderate eye irritation. Harmful if inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

	FIRST AID
If in eyes	 Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or doctor for treatment advice.
lf on skin	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.
if swallowed	 Immediately call a poison control center or doctor. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give ANY liquid to the person. Do not give anything by mouth to an unconscious person.
Have the prod	uct container or label with you when calling a poison control
	or, or going for treatment. You may also contact [phone
	nergency medical treatment information.
	YSICIAN: Contains petroleum distillate – vomiting may cause
aspiration pne	umonia.

(Include WPS for APEX Mushroom Use pattern)

[Personal Protective Equipment (PPE):
Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E F on an EPA chemical resistance category selection chart. Applicators and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical resistant gloves, such as butyl neoprene rubber (≥ 14 mils), nitrile rubber (≥ 14 mils), bamer laminate, or viton (≥ 14 mils). Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.]

Engineering Controls Statements:

When handlers use closed systems or enclosed cabs in a manner that mests the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS: This product is toxic to aquatic dipteran. Using it in a manner other than that described by the label could result in harm to non-target aquatic invertebrates. Do not contaminate water when disposing of rinsate or equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame.

[Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.]

FAGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

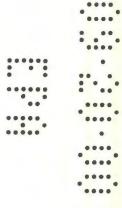
Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls
- Chemical-resistant gloves, such as butyl neoprene rubber (≥ 14 mils), nitrile rubber (≥ 14 mils), barrier laminate, or viton (≥ 14 mils)
- Shoes plus socks

Do not apply this product through any type of irrigation system



(Directions for Use for RF-9811 EC [DIANEX]-Stored Tobacco Products)

INTRODUCTION: Zeecon® RF-342-9811 EC is an emulsifiable formulation of the insect growth regulator, (S)-methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead, it interferes with the normal processes of insect development and prevents adult emergence. Zeecon RF-342 9811 EC, when used according to label directions, controls the following insects:

Almond moth (Ephestia cautella)

Cigarette beetle (Lasioderma serricorne)

Sawtooth grain beetle (Oryzaephilus surinamensis)

Red flour beetle (Tribolium castaneum)

Tobacco moth (Ephestia elutella)

Indian meal moth (Plodia interpunctella)

Lesser grain borer (Rhyzopertha dominica)

Merchant grain beetle (Oryzaephilus mercator)

Confused flour beetle (Tribolium confusum)

Warehouse beetle (Trogoderma spp.)

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply Zeecon RF-342 9811 EC as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zeecon RF-342 9811 EC at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zeecon RF-342 9811 EC to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add Zeecon RF-342 9811 EC, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each usa....

(Directions for Use for DIACON -Stored Product Insects)

PRODUCT INFORMATION: (S)-methoprene, the active ingredient in DIACON®, protects stored grains from damaging insects by interfering with the normal process of insect development. Unlike traditional pesticides, DIACON is not an adulticide, but its residual activity prevents the development of larvae into adults. DIACON, when used according to the label directions, prevents regeneration of the following insects: almond moth, Indian meal moth, cigarette beetle, lesser grain borer, sawtooth grain beetle, merchant grain beetle, red flour beetle, and confused flour beetle. Existing insect populations should be treated fumigated before applying DIACON for residual protection.

If stored grain insect populations exceed 2 insects per <u>1 kg</u> sample during storage, fumigate to avoid grain-damaged kernels from existing insects. <u>Refer to FGIS</u> regulations for stored grain for more information on sampling and insect thresholds.

Stored Grain: For protection of stored food, feed, oil and seed grains against stored grain insects - for optimum results, thoroughly clean and treat grain storage areas prior to storage of grain. DIACON may also be applied as a top-dressing to stored products that have already been placed into bins or storage areas. Use the rate of 2.5 - 5 ppm for this type of application. Avoid flooding of top-dress area.

DIRECTIONS FOR USE

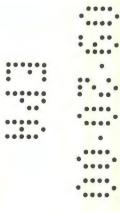
X

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

GENERAL DIRECTIONS FOR TREATMENT OF GRAIN BEING STORED: Dilute DIACON with water or FDA-approved food grade oils* or soybean oil and apply to the moving grain stream as a coarse spray to give a deposit of 5 ppm of DIACON on the grain. Use a final water solution volume of 5 gallons of liquid per 1000 bushels of grain and 10 gallons of liquid per 1000 bushels of rice. Final spray volumes of oil solutions should be applied at the oil manufacturer's rates. Agitation of water or oil solutions is necessary.

For maximum residual and efficacy, use the rate of 5 ppm. For shorter term residual, lower rates may apply, but do not use rates less than 1 ppm.

DIACON is to be applied in solution in accordance with the general directions to stored <u>products</u> at the following rates per 1000 bushels to provide treatment with 5 ppm concentrations of DIACON. <u>When using lower rates, use the appropriate amount of formulation to achieve the desired application rate:</u>



	5 ppm		2.5	ppm 1 p		pm	
	fl oz	ml	fl oz	<u>ml</u>	fl oz	ml	
Wheat	7.70	228	4.0	114	1.54	46	
Com	7.10	212	3.5	106	1.42	43	
Grain sorghum (Milo)	7.10	212	3.5	106	1.42	43	
Barley	6.10	182	3.0	91	1.22	37	
Rice	5.70	170	3.0	85	1.10	34	
Oats	4.10	121	2.0	61	0.80	25	
Peanuts*	3.85	12415	2.0	620	0.80	24	

^{*}For peanuts, use water solution only

USE PRECAUTIONS:

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- Apply DIACON grain protectant only to grain of known treatment history, apply no more than once per crop.
- Check spray equipment calibration regularly to insure proper application rates.
- Add the measured amount of DIACON to a spray tank partially filled with water or mineral oil, mix and complete filling with recommended quantity of carrier.
- Use diluted spray solution within 48 hours of mixing. Agitate before each use.
- Avoid application at extremely dusty sites.

DIACON may also be used as a fogging concentrate or surface spray for the treatment of warehouses, silos, storage bins or other stored commodity areas. For application of DIACON as a fogging or space spray, use the following directions.

Application with Cold Aerosol Generators: Apply DIACON as a mist or aerosol. Dilute with water or oil as required following the instructions of the spray equipment manufacturer. Apply DIACON at the rate of 1 ml per 1000 square feet of surface area or 1 ml per 10 cu ft. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated areas and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of DIACON to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add DIACON, mix a complete filling with recommended quantity of water. Use diluted spray solution within hours of mixing. Agitate before each use.

specified

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(Directions for Use for APEX – Mushrooms)
(S)-methoprene, the active ingredient in APEX® 5€ insect growth regulator (IGR) is a chemical analog of a natural insect hormone. Unlike traditional pesticides, the presence of (S)-methoprene does not result in immediate insect kill, it interferes with the normal process of insect development. APEX 5€ will prevent the emergence of adult sciarid flies when incorporated into the mushroom growing medium. Under most conditions, fly control is achieved without adverse effects on mycelium growth or mushroom yield. Pupae and adults present at the time of application will not be affected. If high adult populations are present initially, use of a conventional adulticide will ensure the best overall results. After treatment with APEX 5€, larvae will continue to develop to the pupal stage where they will die. Estimation of adult fly populations should be no earlier than 2 weeks after treatment to assess the full benefit of APEX 5€.

METHOD, RATE, AND TIMING OF APPLICATION: For best results, APEX 5E should be incorporated in the mushroom growing medium.

Follow either METHOD A, METHOD B, or METHOD C Application Instructions.

A. INCORPORATE IN CASING AT TIME OF CASING
Apply APEX 5E at the rate of 5½ fluid ounces per 1000 sq ft (fl oz/1000 sq ft).
Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after placement.

B. INCORPORATE IN COMPOST AT TIME OF SPAWNING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

In Compost: Apply APEX 5E at the rate of 5½ fl oz/1000 sq ft in adequate water for even distribution. Spray or sprinkle on the surface of compost at the time of spawning and thoroughly incorporate using a spawning machine or other suitable mechanical means.

In Casing: Apply APEX 5E at the rate of 2½ fl oz/1000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

C. COMPOST SURFACE DRENCH BEFORE CASING AND IN CASING AT TIME OF PLACEMENT OF CASING LAYER

For those crops that have a 16-day or longer spawn run, a split application can be used.

First Application, on compost: Apply APEX 5E 12-13 days after spawning. Drench APEX 5E evenly on the surface at the rate of 2¾ fl oz/1000 sq ft in adequate water for even distribution.

Second Application, in casing: Apply APEX 5E at the rate of 2¼ fl oz/1000 sq ft. Make application evenly and mechanically mix into casing material prior to the casing operation, or drench evenly onto the surface of the casing immediately after setting it in place.

MIXING AND HANDLING INSTRUCTIONS

1. Add the measured amount of APEX 5E to a spray tank partially filled with water, mix, and complete filling with recommended quantity of water.

2. Use diluted spray solution within 48 hours of mixing. Agitate before each use.

EFFECT ON MUSHROOMS

, if you In most cases, treatment with APEX 5E has a beneficial effect on mushroom yield through control of damaging sciarid fly larvae. Due to the widely differing practices followed in mushroom culture, the user should conduct test treatments on small plots to determine that reduced crop yields will not occur under his own cultural conditions.

you can

Directions for Use for midges/filter flies

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

MIXING AND HANDLING INSTRUCTIONS:

MIXING AND HANDLING INSTRUCTIONS:

Partially fill spray container with water; then add the recommended amount of RF-9811 EC, agitate, and complete filling. Agitate mildly during application. Agitation can be accomplished by use of recirculation pump, mixer, air pump, or other suitable equipment.

RECOMMENDED APPLICATIONS

Waste Water Treatment Facility Pests: Use RF-9811 EC in trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water treatment facilities where midges, filter flies, and other nuisance aquatic insect pests are a problem.

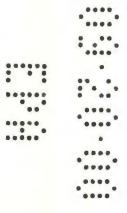
What to Expect in Waste Water Treatment Facilities Continuous Flow Sewage (waste water)

In order to achieve effective results, RF-9811 EC must be applied daily for at least 2 weeks. If applications are not made on a continuous basis, erratic results may occur. Following initial applications of RF-9811 EC, a gradual reduction in the number of adult pests will be seen over approximately a 1 week period. Reduction in adult populations will be very noticeable within a 2 week period following continuous application. Due to varying conditions or heavy infestations, a longer period may be necessary for control. Since the mode of action of RF-9811 EC is to prevent adult emergence, existing adults and pupa present at the time of initial application will complete their life cycle.

As adult suppression peaks, use a maintenance rate of RF-9811 EC for continuous protection from population rebound. However, if application of RF-9811 EC is halted following population suppression, rebound of the population can be expected within 2 to 3 weeks after stopping application. For continuous suppression throughout the pest season, continue applications of RF-9811 EC

Sludge or Solid Waste Applications

For solid waste applications, use the initial high rate. The dilution should be applied until the drying beds have been filled. Following filling of the drying beds, halt the dilution application. Make applications of the dilution at the influent side as the sludge or solids enter into the drying beds. Application of RF-9811 EC to solids will prevent the emergence of adult insect pests thereby keeping infestations under control.



METHODS OF APPLICATION

Waste Water Treatment Facilities: Dilute RF-9811 EC with water prior to use. Apply RF-9811 EC by using a metering pump, drip bucket, or other suitable equipment. Metering pumps are the most efficient and accurate method of application. The application method will influence appropriate product dilution. Depending on the dosage rate, prepare desired volume of dilution to apply over a 24 hour period (day tank), or in cases of sludge beds, applied until the beds have been filled. When using delivery devices, it is important to calibrate the device to deliver the required amount of RF-9811 EC over a 24 hour period. Mix sufficient material in advance to provide for applications longer than 24 hours. Metering pumps that are capable of delivering material for more than 24 hours are highly the best recommended.

APPLICATION RATE

Waste Water Treatment Pests:

Initial Application - 2.5 to 3.0 ounces of RF-9811 EC per 1 million gallons of sewage (waste water) in sufficient water to apply uniformly at the influent side over a 24 hour period.

Maintenance Rate - <u>1.5 to 2.0</u> ounces RF-9811 EC per 1 million gallons of sewage waste water in sufficient water to apply uniformly at the influent side over a 24 hour period.

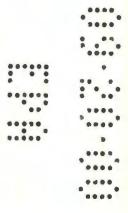
To achieve effective results, use initial application rates on a daily basis for 2 weeks, without interruption. Use sufficient water/RF-9811 EC to achieve uniform application to sewage (waste water) over a 24 hour period. Make application of the dilution at the <u>influent</u> side of the particular area to be treated.]

Maintain initial rate of application for 2 weeks and then for continued effectiveness, follow the directions for the maintenance rate.

APPLICATION SITES

Waste Water Treatment Facilities: Make applications of RF-9811 EC to sewage as it <u>flows into</u> trickling filters, sludge drying beds, clarifiers, holding ponds, lagoons, influent structures, stagnant or standing water, or other areas of waste water facilities where pests are a problem.

Make RF-9811 EC applications as the sewage enters (influent areas) the targeted processing area. Failure to add the material at the influent side may result in erratic results.



STORAGE and DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Storage - Store in a cool dry place. Pesticide Disposal - Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

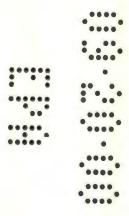
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FAX

Wellmark International

Regulatory Affairs 1100 East Woodfield Road Suite 500 Schaumburg, IL 60173



To: Jim Downing

EPA / BPPD

Tel:

FAX: (703) 308-9071 \$7026

From: Steve Spaulding

Tel: (847)330-5380 FAX: (847)330-5315

Pages: 8 (including cover page)

CC:

File: 2724-427

Date: September 27, 2001

If you do not receive all pages of this fax, please call (847)330-5380

SUBJECT: RF-342 Emulsifiable Concentrate (EPA Reg. No. 2724-427)
Environmental Hazard Statement Revision

Dear Jim:

Per our discussion yesterday concerning revisions to the Environmental Hazard Statement on the amended label for 2724-427, I have attached the following background documentation:

- Agency letter received on August 5, 1996 indicating that all methoprene products are supported for reregistration. On page 2, the letter states that aquatic invertebrate labeling restrictions are required on all methoprene products applied to water until the Estuarine Invertebrate Life Cycle Study is completed. I have placed an asterisk beside all methoprene products applied to water on the master list that will be affected by this statement.
- Submission of S-Methoprene Reports in Support of Resolution of Aquatic Hazard Label Statements dated May 23, 1996 including the Chronic Mysid Shrimp Study (MRID44022101) satisfying requirements for the Estuarine Invertebrate Life Cycle Study.

Nancy will be submitting by e-mail the revised label for 2724-427 removing the aquatic invertebrate statements and correcting other language per our discussion yesterday. Please contact me if you have any questions.

Best Regards,

Steven R. Spaulding

Manager, Regulatory Affairs



. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460



2724-427 CY 08PH

Reregistration

Mr. Steven R. Spaulding Sandoz Agro, Inc. 1300 East Touhy Avenue Des Plaines, Illinois 60018-3300 RECEIVED

AUG - 5 1996

REGULATORY APPAIRS

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Dear Mr. Spaulding:

Subject: Methoprene Product Supported for Reregistration (See attached list of products covered by this letter)

Thank you for your letter and transmittal dated April 22, 1996, submitted in response to the Agency's [Willie H. Nelson's request of March 20, 1996] requesting verification of all methoprene products supported by registration. As a follow-up to this request, the items listed below are items which must be completed before reregistration of these products can be completed.

The Biopesticides and Pollution Prevention Division (BPPD) has reviewed the files for methoprene products in an attempt to complete the reregistration process for these products, and to assist in this attempt the following information is required:

- a. Application for reregistration (use EPA Form 8570-1). Complete and sign this form. In Section II of this form, check the box "Other" and insert the phrase "Application for Reregistration" in the Explanation box.
- b. Submit five (5) copies of revised draft label and labeling. Include on the label all changes specified by the RED for methoprene products, e.g.: LABELING REQUIREMENTS FOR END-USE PRODUCTS and LABELING REQUIREMENTS FOR MANUFACTURING USE PRODUCTS (see attached methoprene information sheet).
- c. All applicable methoprene products must comply with requirements for Worker Protection Standard" according to PR Notice 95-3 (see attached).

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d. Submit two (2) copies of the current Confidential Statement of Formula (CSF) (EPA Form 8570-4, revised February 85). Two completed and signed CSF forms must be submitted for the basic formulation and for each alternate formulation for each affected product. If CSFs are not provided for the alternate formulas, they will not be registered and will no longer be acceptable. Instructions for completing the CSF form is found in the Appendix of the Pesticide Reregistration Handbook sent out with the RED.

Until the Estuarine Invertebrate Life Cycle Study review is completed and found acceptable, and it is determined that methoprene poses no problem when used in aquatic applications, labeling restrictions will have to remain on the labeling:

"This product is toxic to aquatic invertebrates. Using it in a manner other than that described by the label could result in harm to aquatic invertebrates. Do not contaminate water when disposing of rinsate or equipment washwaters"

Should you have any questions concerning this letter, please free to contact Mr. Willie H. Nelson at (703) 308-8682.

Sincerely,

How Chow

Janet L. Andersen, Acting Direstor Biopesticides and Pollution Prevention Division (7501W) (3)

PRODUCT MASTER LIST - METHOPRENE

- Zoecon RF-275 Pressurized Spray EPA Reg. No. 2724-338
- Zoecon RF-291 Emulsifiable Conc. EPA REG. No. 2724-352
- 3. Zoecon RF 293 Methoprene Bolus for Beef & Dairy Cattle EPA Req. No. 2724-356
- 4. Zoecon RF 297 Aerosol EPA Reg. No. 2724-360
- 5. ALTOSID CP-10 (cattle premix 10%) EPA Reg. No. 2724-367
- Zoecon Granular IGR Cattle Supplement EPA Reg. No. 2724-372
- 7. Zoecon Block IGR Cattle Supplement EPA Reg. No. 2724-373
- 8 Altosid Briquets EPA Reg. No. 2724-375
 - 9. Kabat Tobacco Protector Conc. EPA Reg. No. 2724-377
 - 10. Kabat Tobacco Protector Conc. , EPA Reg. No. 2724-384
- # 11. Altosid Liquid Larvicide EPA Reg. No. 2724-392
- * 12. Altosid Liquid Larvicide Conc. EPA Reg. No. 2724-393
 - 13. Zoecon RF-299 RTU Carpet Pump Spray EPA Reg. No. 2724-401
 - 14. Zoecon RF-322 Ovicidal Pump Spray EPA Reg. No. 2724-404
 - 15. Zoecon RF-329 Ant Growth Regular EPA Reg. No. 2724-420
- # 16. Zoecon RF-292 Briquet EPA Reg. No. 2724-421

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- 17. Zoecon RF-372 Collar EPA Reg. No. 2724-426
- 18. Zoecon RF-342 Emulsifiable Conc. EPA Reg. No. 2724-427
- 19. Methoprene Technical EPA Reg. No. 2724-441
- 20. S-Mehtoprene Technical EPA Reg. No. 2724-442
- * 21 Zoecon RF-379 Mosquito Growth Regulator SR-20 EPA Reg. No. 2724-446
- ¥ 22. Zoecon RF-330 Altosid Pellets EPA Reg. No. 2724-448
- * 23. Altosid Granules
 EPA Reg. No. 2724-ULR 451
 - 24. Zoecon Apex 5E EPA Reg. No. 2724-452
 - 25. Zoecon 9026 Fogger EPA Reg. No. 2724-454
 - 26. Zoecon 9202 Aerosol EPA Reg. No. 2724-455
 - 27. Zoecon 9007 Concentrate EPA Reg. No. 2724-459
 - 28. Zoecon 9207 Collar EPA Reg. No. 2724-460
 - 29. Zoecon 9307 Pump Spray EPA Reg. No. 2724-462
 - 30. Sandoz 9309 Fogger EPA Reg. No. 2724-464
 - 31. Sandoz 9311 Aerosol EPA Reg. No. 2724-465
 - 32. Sandoz 9412 Mousse Lite EPA Reg. No. 2724-467

SANDOX AGRO, INC. 1300 EAST TOUHY AVENUE, DES PLAINES, ILLINOIS 60018-33,00

RECD EPA/GPP/DPD2



May 23, 1996



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CORPORATE HEADQUARTERS

TEL. 847.699.1616

Environmental Protection Agency
Office of Pesticide Programs (H7505C)
Document Processing Desk
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Attn: Mr. Willie Nelson

Subject: Submission of S-Methoprene Reports in Support of Resolution of

Aquatic Hazard Label Statements.

Products: Altosid Liquid Larvicide (A.L.L.) - EPA Reg. No. 2724-392

A.L.L. Concentrate - EPA Reg. No. 2724-446 Altosid Briquets - EPA Reg. No. 2724-375 Altosid XR Briquets - EPA Reg. No. 2724-421 Altosid Pellets - EPA Reg. No. 2724-448

Altosid Granules - EPA Reg. No. 2724-ULR 451

Please find enclosed 3 copies of the following reports in support of resolution of aquatic hazard label statements for the above referenced mosquito control products containing S-Methoprene:

- (S)-Methoprene Technical Chronic Toxicity to Mysids (Mysidopsis bahia)
 Under Flow-through Conditions. SLI Report #96-2-6378. Springborn
 Laboratories, Inc. April 2, 1996.
- An Assessment of Non-Target Effects of the Mosquito Larvicides, Bti and Methoprene, in Metropolitan Area Wetlands. A Report from the Scientific Peer Review Panel to the Metropolitan Mosquito Control District (MMCD). January, 1996.
- 3. Methoprene (Altosid) Label Issues Position Summary. Sandoz Agro, Inc. May, 1996.

P.06



The Mysid Life-Cycle Toxicity Test was successfully completed after two previous studies were determined by EPA to be invalid due to poor population survival rates and poor reproduction success in the control groups. The Maximum-Acceptable-Toxicant Concentration (MATC) was calculated to be >14 and <25µg A.I./L, which is similar to the values reported in the previous 2 invalid studies. This study has been repeated in response to your letter of July 20, 1994 in order to fulfill Guideline 72-4 requirements for an estuarine invertebrate chronic toxicity study.

The MMCD study evaluated potential effects of methoprene on non-target organisms after repeated use and failed to find any significant effects on birds, amphibians, zooplankton and most non-target insects.

The Methoprene Label Issues Position Summary provides rational for our request to: (1) remove the warning statement "Do not apply to fish-bearing waters" from all solid Altosid mosquito control products and (2) add the statement "This product is toxic to aquatic dipteran (mosquitoes) and chironomid (midge) larvae" to all Altosid mosquito control products.

We would like to request a followup meeting with the BPPD following review of the submitted information in order to reach final resolution of this issue. Please contact me at (847)390-3007 if you have any questions.

Yours Sincerely, SANDOZ AGRO, Inc.

Steven R. Spaulding

Sr. Regulatory Specialist



TRANSMITTAL DOCUMENT

SUBMITTED BY

Sandoz Agro Inc. 1300 E. Touhy Ave. Des Plaines, Illinois 60018

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Submission of reports in support of resolution of label issues for Altosid mosquito control products.

TRANSMITTAL DATE

May 23, 1996

LIST OF SUBMITTED STUDIES

Volume 1	(S)-Methoprene Technical - Chronic Toxicity to Mysids (<i>Mysidopsis bahia</i>) Under Flow-through Conditions. SLI Report #96-2-6378. Springborn Laboratories, Inc. April 1996.
	MRID No. 44022101
Volume 2	An Assessment of Non-Target Effects of the Mosquito Larvicides, Bti and Methoprene, in Metropolitan Area Wetlands. A Report from the Scientific Peer Review Panel to the Metropolitan Mosquito Control District. January, 1996.
,	MRID No. 44022102
Volume 3.	Methoprene (Altosid) Label Issues - Position Summary. Sandoz Agro, Inc. May, 1996. MRID No. 44022103
	MRID No. 7 7 022105
COMPANY C	OFFICIAL: Steven R. Spaulding Sk Spaulding

SANDOZ AGRO, INC.

COMPANY NAME:

COMPANY CONTACT:



For protection of stored tobacco from damage by Cigarette Beetle (Lasioderma serricorne) and Tobacco Moth (Ephestia elutella)

TOTAL: 100.0%
This product contains 2.5 lb/gallon (300 grams/liter)
(S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN
CAUTION
SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

33.8 FL OZ (11)

37613B

INTRODUCTION: DIANEX® Emulsifiable Concentrate (DIANEX) is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (§)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. DIANEX, when used according to label directions, controls the following insects: Cigarette beetle (Lasioderma serricorne) and Tobacco moth (Ephestia elutella).

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS—CAUTION: Harmful if Inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes, or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if fritation persists.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of rinsate or equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame.

DIRECTIONS FOR USE It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard. Application with Cold Aerosol Generators: Apply DIANEX as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply DIANEX at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment to achieve uniform treatment. Close room or watehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as an Aquenus Spray Prepare a diluted spray solution by adding 1 ml of DIANEX to 1 callon of water. Apply at a

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of DIANEX to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add DIANEX, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

STORAGE AND DISPOSAL: Do not contaminate water, food, or feed by storage or disposal. Storage- Store in a cool, dry place. Pesticide Disposal- Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal- Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND CONDITIONS OF SALE: Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

For information call 1-800-248-7763

Wellmark

EPA Reg. No. 2724-427 EPA Est. No. 2724-TX-1 Made is USA

DIANEX® Emulsifiable Concentrate for Tobacco is a registered trademark of Wellmark International

Bensenville, Illinois 60106

© 1998 Wellmark International 376158

Wellmark

October 8, 2001

Mr. James Downing
Office of Pesticide Programs 7504C
U.S. Environmental Protection Agency
Room 910 Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, Virginia 22202

SUBJECT:

FINAL PRINTED LABELS FOR EPA STAMPED APPROVED

(9/22/97-REREGISTRATION) FOR

ZOECON® RF-342 (RF9811) EMULSIFIABLE CONCENTRATE

EPA REG. NO. 2724-427

Dear Jim:

Per our phone conversation on October 5, I've enclosed 3 copies of final printed labeling related to the methoprene reregistration label that was stamped approved on 9/22/97. Hopefully, this will allow you to finalize this project and provide a stamped label for the amended formulation. If you need anything further, give me (847) 330-5376 or Steve (847) 330-5380 a call.

Yours sincerely,

WELLMARK INTERNATIONAL

Mancy Huebl

Nancy Huebl

Regulatory Specialist

Enclosure

cc: S. Spaulding

Please read instructions on reverse before completing					For	m Appared. O	MB No. 2070	0-0060. Approval expires 2-28-95		
Environmental Protection Washington, DC 20						Amendment X Other		OPP Identifier Number		
		Ap	plica	ation for Pesticide - S	ection I					
Company/Product Number Wellmark International/272	4-427			EPA Product Mar Jim Downing	nager		3. Proposed Classification			
Company/Product (Name) Weilmark International/Z Co	oecon RF-342 Emulsifi ncentrate	able		PM # Biopesticides			X None Restricted			
Name and Address of Applicant / Registrant (Include ZIP Code) Wellmark International 1100 E Woodfield Road Schaumburg IL 60173 Check if this is a new address				6. Expedited Review. In accordance with FIFRA Section 3(C)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name						
Section - II										
Amendment - Explain below. Resubmission in response to Agency letter dated Notification - Explain below. Explanation: Use additional page(s) if necessary. (For section I and section II.)										
		-:		Section - III						
4. Allestedal This Deaduct 1960	he Deskood lee			Section - III		· · · · · · · · · · · · · · · · · · ·				
1. Material This Product Will Child Registent Reskaring	Unit Packaging	 -		Water Soluble Packaging		2. Type of C	ontainer			
Child-Resistant Packaging Yes No	Yes X No	No. pe	 er	Yes Valer Soluble Packaging Yes No If "Yes Unit	No. per	X PI	etal astic lass aper			
* Certification must be submitted	Packaging wgt.	contai	ner	Packaging wgt.	container	0	ther (Specify	0		
3. Location of Net Contents In	formation ontainer	4. Size(s)	Retai	Container 5. Location of Label Dire						
6. Manner in Which Label is A	ffixed to Product	x	Lithog Paper Stenc	glued						
				Section - IV						
1. Contact Point (Complete	items directly below for it	ientificati	on of	individual to be contacted, in	f necessary	, to process this	application	n.)		
Name Nancy Huebl			1	Title Regulatory Specialist			Telephone 847 330 5	No. (Include Area Code) 5376		
Certific			rtifica	cation				6. Date Application		
I certify that the statements I have made on this form and all a acknowledge that any knowingly false or misleading statemen under applicable law.							•••••	Received (Stamped)		
2. Signature Many Hubl			- 1	3. Title Regulatory Specialist			••••	•••••		
4. Typed Name Nancy Huebl				5. Date October 8, 2001				••••		

Label Review Sheet							
FILENAME:	g:regulatory\LABELS\CAHS PEC\02724427\fpl for downng for rereg label 1001	COVERSHEET UPDATE:	October 2001				
PRODUCT:	ZOECON RF-342 EMULSIFIABLE CONCENTRATE FOR TOBACCO	EPA REG. NO.:	2724-427				
APPROVED:	9/22/97	SUPERSEDES:	12/19/90				

OVERVIEW: FPL LABEL (SUBMITTED FOR METHOPRENE REREGISTRATION) LABEL/NOMINAL/NAME CHANGE SANDOZ TO WELLMARK				
Page #	Description of Major Changes			

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[Optional text]

ZOECON RF-342 EMULSIFIABLE CONCENTRATE FOR TOBACCO Alternate Brand Name: DIANEX® Emulsifiable Concentrate for Tobacco

[For protection of stored tobacco from damage by Cigarette Beetle (*Lasioderma serricorne*) and Tobacco Moth (*Ephestia elutella*)]

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Storage Facilities

ACTIVE INGREDIENT:

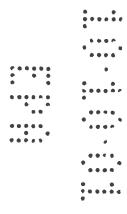
This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements.

NET CONTENTS:



INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects.

Almond moth (Ephestia cautella)
Cigarette beetle (Lasioderma serricorne)
Sawtooth grain beetle (Oryzaephilus surinamensis)
Red flour beetle (Tribolium castaneum)
Tobacco moth (Ephestia elutella)
Indian meal moth (Plodia interpunctella)
Lesser grain borer (Rhyzopertha dominica)
Merchant grain beetle (Oryzaephilus mercator)
Confused flour beetle (Tribolium confusum)
Warehouse beetle (Trogoderma spp.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Harmful if inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of rinsate or equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS; Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in area where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

Storage - Store in a cool, dry place. **Pesticide Disposal** - Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. **Container Disposal** - **[Metal Containers]**: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. **[Plastic Containers]**: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. **[Glass Containers]**: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Wellmark International Bensenville IL 60106 Made in USA

EPA Reg. No. 2724-427 For information, call 1-800-XXX-XXXX. EPA Est. No.:

DIANEX® Emulsifiable Concentrate for Tobacco is a registered trademark of Wellmark International.

255,700 300

Kelly Parker Toecon Corporation A Sandoz Company 12005 Ford Road, Suite 800, LB 44 Dallas, TX 75234-7296

Subject: Secon RF-342 emulsifiable Concentrate
EPA Registration No. 2724-427
Changes in the DIRECTIONS FOR USE portion of the
label as per our discussion on November 21, 1989.

Dear Relly:

The labeling changes that we discussed on November 21, 1989 made in connection with registration under the federal Insecticide, fungicide and Rodenticide Act, as amended, are acceptable. The following DIRECTIONS FOR USE label statements will be removed because they would not be achievable in tobacco processing plants:

"Cover or remove any tobacco or tobacco processing equipment during application. After spraying wash all equipment, benches, shelving, etc., where tobacco will be handled with an effective cleaning compound followe! by a potable water rinse."

Submit five (5) copies of the final printed labeling.

Sincerely,

Phil Hucton
Product Manager 17
Insecticide/Rodenticide Branch
Registration Division (H7505C)

CONCURRENCES

SYMMOL

BATE

DATE

DATE

DATE

SPA Form 1226-1 (12-78)

OFFICIAL FILE COPY

MAME OF PERTACIDE PRODUCT NOTICE OF PESTICIDE: RESISTRATION RESESTINATION Zoecon RF-342 Emulsifiable Concentrate (Under the Faderal Insecticide, Fundicide, and Redepticide Act, as assended) HAME AND ADDRESS OF REGISTRANT Combide 21F model Zoecon Corporation A Sandoz Company 12005 Ford Boad, Suite 800, LE 44 Dallas, TX 75234-7296 NOTE: Changes in labeling formule differing in substance from that accepted in connection with this registration ment be submitted to and accepted by the Registration Division prior to use of the label in commerce, is any correspondence on this product always refer to the above U.S. EPA registration number. On the basis of information furnished by the registrant, the above asked praticide is inverby Registered/Resignated under the Federal Insecticide, Fungicide, and Rolemicide Act. A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith. Regintration is in no very to be construed as an indensement or approval of this product by this Agumy, in order to protect beath and the derivousint, the Administrator, on his motion, say at any time suspend or cancel the registration of a practicide in accordance with the Act. The acceptance of any name in consection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the same or to its one if it has been covered. This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you: 1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) When the Agency requires all registrents of similar products to submit such data. 2. Make the labeling changes insted below before you release the product for shipsent: a. Add the phrase "P-A Registration No. 2724-427." i. And the following statements to the DIDICTIONS FOR USE portion of the latel: The not apply directly to tobacco peigg processed at fover or remove any tobacco or coffeet processing equipment during application. recent to the same all and reent, fondown, (i) in the contract twice of ill the contract. tion at expertise cleaning emipoun, inclosed - intelled for girke." BEST AVAILABLE COPY ATTACHMENT IS APPLICABLE PARTIQUE COITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED 50588;I:CR-31:Bagley:H-01:KENCO:11/08/89:12/19/89:Aw:6W:VO:EX:&w

c. The following statement must be added to the label after the HARANDS TO EUNIANS AND DOMESTIC ANIMALS portion of the label;

ENVIRONMENTAL MAXABOS

Do not contaminate water when disposing of equipment weakwaters.

d. You must add the following statement to the use directions:

Do not use this product in or on electrical equipment due to the possibility of shock hazard.

This statement must be included until your submission of test data indicates that the product is safe to use near or on electrical equipment.

- Include data on the corrowive characteristics of the product when yor exhait the rest of the storage stability data.
- 4. Subsit five (5) copies of your final printed Labeling before you release the product for shipment. Refer to the λ -79 enclosure for a further description of final printed Labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Phil Button

Product Manager (17)

Insecticide-Rodenticide Branch Registration Division (H7505C)

2nclosures

ZOECON RF-342 EMULSIFIABLE CONCENTRATE FOR TOBACCO

An Insect Growth Regulator for the Control of Insect Posts in Tubacco Processing and Storage Facilities

This product contains 2.5 lb/gallon (200 grams/liter)
(§)-methoprane active ingredient.

KEEP OUT OF REACH OF CHILDREN COMENTS to the Date Pared

CAUTION

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Under the course incorned Art as Paracide, and hoderschold Art as smoother, for the Statistica registered under EPA ling. No.

See Buck Fanel for Addibional Pracautionary Statements.

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EPA Nog. No. 2724-V.S. Paterts 3,904,642 & 3,912,615 87896.3236

DA 242, 54017-CA-1 State (4 STA 4 1988 20040

Wellmark International

451137-00

Wellmark

May 3, 2000

Ms. Kate Bouve FIFRA 6(a)(2) Office of Pesticide Programs (H7504C) U.S. Environmental Protection Agency 1921 Jefferson Cavis Hwy. Arlington, VA 22202

Subject:

FIFRA 6(a)(2) REPORTING (STUDY SUBMISSION) FOR ZOECON RF-342 EMULSIFIABLE CONCENTRATE EPA REG. NO. 2724-427

Dear Ms. Bouvé:

Wellmark International is submitting a primary eye irritation study in rabbits under provision of FIFRA Section 6(a)(2) for EPA Reg. No. 2724-427. Three copies of the study are enclosed along with a Transmittal Document.

In the primary eye irritation study in rabbits #SLS 3122.8, one of six rabbits in the non-wash, treated group exhibited corneal involvement up to day 21 post-dosing. The remaining five of six rabbits in the non-wash, treated group had eye irritation that cleared by day 10. In the washed, treated group, all animals had minimal eye irritation at 72 hours and no irritation at day 4. Although the study results indicate that this formulation would be a severe eye irritant (tox cat. I), it is important to note that. Wellmark has yet to receive an adverse incident report for this current formulation. Additionally, this product is marketed to a specialized niche group that has many years of experience with this product's application.

This study was conducted in anticipation of methoprene end-use product reregistration data requirements. However, ultimately the study was not required for reregistration and inadvertently it was not submitted. This fact was recently discovered when reviewing the product data base in relation to a formulation amendment required for reasons unrelated to eye irritation. Wellmark with be submitting this formulation amendment with an ocular irritation study in the third quarter 2000.

Please contactime at (630) 227-6017 should you have any questions regarding this automission.

Sincerely.

Nancy Huebl

Regulatory Labe: Specialist

Maning which

Enclosures:

SLS Study No. 3122.8 (Eye)

CC.

S. Spaulding/C. Elmi/D. Crawford

TRANSMITTAL DOCUMENT

SUBMITTED BY

Wellmark International 1000 Tower Lane Bensenville, Illinois 60160

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Submission of Primary Eye Irritation study for Dianex RF-342 EC in Compliance with FIFRA 6(a)(2) Reporting Requirements

TRANSMITTAL DATE

May 3, 2000

LIST OF SUBMITTED STUDIES

Primary Eye Irritation Study of Dianex RF-342 in Rabbits, Volume 1 of 1 Springborn Life Sciences, Inc. study # 3122.8, 2/13/89. MRID# 45113701

COMPANY OFFICIAL:

Nancy Huebl

Mancy Thick! Registration Specialist

COMPANY NAME:

Wellmark International

COMPANY CONTACT:

Nancy Huebl (630) 227-6017

Springborn Lite Sciences, I
Toxicology & Human Safety Division
553 North Broadway • Spencerville, Ohio 45887 • (419) 647-4196 • Telex 4436041 • Facsimile 419-647-6560

1882h CORP.

PRIMARY EYE IRRITATION STUDY OF DIANEX RF-342 IN RABBITS (EPA)

FINAL REPORT

451137-01

Data Requirement

Guideline 81-4

Author

Joseph C. Siglin, B.A.

Study Completed on

February 13, 1989

Performing Laboratory

Springborn Life Sciences, Inc. (SLS) Toxicology and Human Safety Division 553 North Broadway Spencerville, Ohio 45887

SLS Study No.

3122.8

Submitted To

Zoecon Corporation 12005 Ford Road, Suite 800 Dallas, TX 75234

> Page 1 of 21 Valume / of / Copy 3 of 3

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LETTERS AND REPORTS 51 "Chom sale Sciences, inclined Springpoin Laboratories and reports the state the evolution are grate creme to more they are expressed for dudations want reports. The of the Springpoin Life Sciences feet and Springpoin Laboratories fig. name is before the expressed surror and income so provided for the expressed surror and income so provided in the control of the society of the Springpoin Life Sciences had an or syndycal and are not excepted in indication of the dudation of acceptable services and income and in the control of the control of the services and income and in the control of the services and income and income and in the control of the services and income and incom



MAR 1 2 1999

Ms. Nancy Huebl Regulatory Label Specialist Wellmark International 1000 Tower Lane, Suite 245 Bensenville, Illinois 60106

SUBJECT: Notification of Alternate Brand Names:

Altosid Liquid Larvicide - EPA Reg. No. 2724-392

Zoecon RF-342 Emulsifiable Concentrate - EPA Reg. No. 2724-427

Sandoz 9404 Spray - EPA Reg. No. 2724-483

Your submission of February 16, 1998

Dear Ms. Huebl:

The alternate brand names listed below, submitted in connection with the abovereferenced product registrations, are acceptable and our records have been adjusted to reflect these additional names. This acceptance is given with the understanding that the label for the alternate brand name will be like the registered label in every particular way except for product name, associated artwork, and you may delete, but not add sites and pests.

EPA Registration Nos.
2724-392
2724-427
2724-483

Sincerely yours,

Janet L. Andersen, Ph.D.

Director

Biopesticides and Pollution

Prevention Division (7511C)

DGregory: 703-308-8681:03/08/99: #StMethoprene(Isopropy)(2E, #E, 7S)-11-Metoxy-3, 7, 11

	CONCURRENCES							
SYMBOL	7571C							
SURNAME	6-enory							
DATE	3/8/99							
EPA Form	1320-14 (1/90)			Printed on Demoles	/ Paran	,	OFFICE	AL FILE COPY

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BPPD PRAT ACTION COPING FORM

PM 90: Janet Andersen	REVIEWER: (ASSIGNED BY: 5005000)
EPA REG./FILE SYMBOL 2724483	
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Date on Application	
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Restricted Use: Yes No	Dus
Manufacturing Use: Yes No	atoxiate pare
Exclusive Use: Yes No	1 1 M
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February 16, 1998

Document Processing Desk (NOTIF) Office of Pesticide Programs H7504C U.S. Environmental Protection Agency Room 266A Crystal Mall 2 1921 Jefferson Davis Highway Arlington, Virginia 22202

ATTENTION: R. Sjoblad

SUBJECT:

NOTIFICATION OF ALTERNATE BRAND NAMES

ALTOSID LIQUID LARVICIDE/EPA REG. NO. 2724-392

ZOECON RF-342 EMULSIFIABLE CONCENTRATE/EPA REG. NO. 2724-427

SANDOZ 9404 SPRAY/EPA REG. NO. 2724-483

Dear Mr. Sjoblad:

Enclosed are completed EPA Forms 8570-1 to serve as notifications of the following alternate brand names:

2724-392

ZOECON® ALTOSID® Liquid Larvicide Mosquito Growth Regulator

2724-427

DIANEX® Emulsifiable Concentrate for Tobacco

2724-483

PRECOR® 2000 Premise Spray II

If you have any questions, please, call me directly at 630/227-6017. Thank you for your assistance in this matter. 847-330-5376

Yours sincerely,

WELLMARK INTERNATIONAL

Regulatory Label Specialist

enclosure

CC:

S. Spaulding/C. Elmi

Please read instruction	s on reverse before company form.	Form	Approve DMB No	. 2070-006	O. Approval expires 2-28-95
\$EPA	United States Environmental Protection Washington, DC 20460	•	Regist Amend		OPP Identifier Number
	Application	for Pesticide - S	Section I		
Company/Product No Wellmark Internation		2. EPA Product R. Sjoblad	Manager	1 —	posed Classification
4. Company/Product (N Wellmark Internation	name) nal/ALTOSID Liquid Larvicide	PM# Biopesticides	#9187		, nostroted
5. Name and Address of Wellmark Internation 1000 Tower Lan Bensenville, IL	e		uct is similar or ide		FIFRA Section 3(c)(3) mposition and labeling

d Classification Restricted A Section 3(c)(3) tion and labeling Check if this is a new address **Product Name** Section - II Amendment - Explain below. Final printed labels in repsonse to Agency letter dated Resubmission in response to Agency letter dated _ "Me Too" Application. Notification - Explain below. Other - Explain below. Explanation: Use additional page(s) if necessary. (For section I and Section II.) Notification of alternate brand name: ZOECON ALTOSID Liquid Larvicide Mosquito Growth Regulator Section - III 1. Material This Product Will Be Packaged In: Child-Resistant Packaging Unit Packaging Water Soluble Packaging 2. Type of Container Yes Metai Yes Yes Plastic No No No Glass Paper If "Yes" No. per If "Yes" No. per Certification must Unit Packaging wgt. Package wgt container container Other (Specify) be submitted 3. Location of Net Contents Information 4. Size(s) Retail Container 5. Location of Label Directions 5 oz to 5 gal On label 6. Menner in Which Label is Affixed to Product Lithograph Paper glued Stenciled Section - IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) Telephone No. (Include Area Code) 630 227 6017 C C C C C Nancy Huebl Regulatory Label Specialist 6. Date Application Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowlingly false or misleading statement may be punishable by fine or imprisonment or (Stamped) both under applicable law. Regulatory Label Specialist 4. Typed^¹Name 5. Date Nancy Huebl February 16, 1998 EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original)

	•	•		
Mease	read instructions	on reverse	before con	na form

United States

	Registration
	Amendment
~	Other

OMB No. 2070-0060, Approval expires 2-28-95 **OPP Identifier Number**

SEPA	Environmental Protecti Washington, DC 20	•	Amendment Other	259579
	Applicati	on for Pesticide - Sec	tion I	
Company/Product Number Wellmark International/	/2724-427	2. EPA Product Man R. Sjoblad		Proposed Classification None Restricted
	/ RF-342 Emulsifiable Concent	trate PM# Biopesticides H	٢)	
5. Name and Address of App Wellmark Internation 1000 Tower Lane Bensenville, IL 601	nal	(b)(i), my product to: EPA Reg. No	is similar or identical in	rith FIFRA Section 3(c)(3) composition and labeling
9,,000	(12 8 118 W GOOD 633	Product Name Section - II		
Amendment - Explain Resubmission in resp Notification - Explain	ponse to Agency letter dated	Final printe Agency let	od labels in repsonse to ter dated Application. plain below.	
	nal page(s) if necessary. (For section de name: DIANEX Emulsifiable Concer			······································
1. Material This Product Will	il Be Packaged in:	00011011		
Child-Resistant Packaging Yes No Certification must be submitted	Unit Packaging Yes No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging Yes No If "Yes" No. per Package wgt Containe	2. Type of Contain Meta Plast Glass Pape Othe	ał tic s
3. Location of Nat Contents Lebel C	Information 4. Size(s) Re	etail Container 1-128 oz	5. Location of Label Dire On label	ctions
6. Menner in Which Label is		graph Othe r glued ciled	or	L
		Section - IV		
1. Contact Point (Complete	items directly below for identification	on of individual to be contacted,		
Name Nancy Huebl		Title Regulatory Label Specialist	် Telic ph 630 22	rône No. (Include Area Code) 27 6017 (, , , , , ,
f certify that the states I acknowledge that an both under applicable	Certification of the control of the	d all attachments thereto are true	e, accurate and complete. ine or imprisonment or	6. Date-Application Received (Stamped)
2. Signature	huebl	3. Title Regulatory Label Specialist		
4. Typed Name Nancy Huebl		5. Date February 16	, 1998	

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Please	raali ir	structions	on	reverse	before	company	ina	forn

Form Approved, OMB No. 2070-0060, Approval expires 2-28-95

United States

	Registration
	Amendment
~	Other

OPP Identifier Number

·	gton, DC 20460	ncy	✓ Amendm ✓ Other	ent	259579
	Application for I	Pesticide - Sect	ion I		
Company/Product Number Wellmark International/2724-483 Company/Product (Name)		2. EPA Product Mana R. Sjoblad			posed Classification None Restricted
Wellmark International/Sandoz 9404 Sprav	,	PM# ## Biopesticides	'(
5. Name and Address of Applicant (Include ZIP Cod Wellmark International 1000 Tower Lane Bensenville, IL 60106	(e)		similar or identic	cal in con	FIFRA Section 3(c)(3) inposition and labeling
Check if this is a new address		Product Name _			
	Sec	tion - II			
Amendment - Explain below. Resubmission in response to Agency letter of Notification - Explain below.	dated	Final printed Agency lette "Me Too" A	pplication.	to	
Explanation: Use additional page(s) if necessary Notification of alternate brand name: PRECOR 2000		ction II.)			
	Sect	ion - III			
1. Material This Product Will Be Packaged In:					
Child-Resistant Packaging Yes No * Certification must be submitted Unit Packaging Yes No If "Yes" Unit Packaging Unit Packaging Unit Packaging	No. per container Packag		2. Type of C	Container Metal Plastic Glass Paper Other (Sp	pecify)
	4 Ci-(a) Catall Catal		5. Location of Labe	I Discotiss	
Label Container	4. Size(s) Retail Contai 12-16	1	On label	i Direction	19
6. Manner in Which Label is Affixed to Product	Lithograph Paper glued Stenciled	Other			
	Sect	ion - IV			
1. Contact Point (Complete items directly below for	r identification of indivi	dual to be contacted, i			
Name Nancy Huebl	Title Regulato	ory Label Specialist	ļ* (630 227 60	No. (Include Area Code)
I certify that the statements I have made on to acknowledge that any knowlingly false or no both under applicable law.			and the second s	piste.	6. Vate Application Received (Stamped)
2. Signature Marcy Shell	3. Title Regulator	y Label Specialist			
4. Typed Name Nancy Huebl	5. Date	February 16,	1998		

ES ENVIRONMENTAL PROTECTION ENVIRONMENTAL PROTECTION AGENCY



Office of Pesticide Programs Registration Division (H7505C) 401 "M" St., S.W. Washington, D.C. 20460

NOTICE OF PESTICIDE:

___ Registration

(under FIFRA, as amended) X Reregistration

Number

Date of Issuance:

2724-427

Term of Issuance:

Unconditional Reregistration

Name of Pesticide Product:

Zoecon RF-342 Emulsifiable Concentrate

Name and Address of Registrant (include ZIP Code):

Wellmark International 1000 Tower Lane Suite 245 Bensenville, IL 60106

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EFA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

Based on your response to the Reregistration Eligibility Document(s), EPA has reregistered the product listed above. Enclosed is a copy of your label stamped "Accepted". This action is taken under the authority of section 4(g)(2)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended. Reregistration under this section does not eliminate the need for continual reassessment of pesticides. EPA may require submission of data at any time to maintain the registration of your product.

	Wnelson: 09/21/97:308-8682:EPA reg.no. 2724-427:methoprene							
	Cionature of D	pproving Officia	1. 1	CONCURRENCE	5	Date	200 00	1007
SYMBOL	7511W	751/W)	22/1				SEP ZZ	1001
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DATE	9/20/91	9/22/97		***************************************	***************************************	***********	**************	
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WITED STATES

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTA SEGUETTO CO. 20460
Office of Pestilide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

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____ Registration

(under FIFRA, as amended)

_ Reregistration

Number

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2724-427

SFP 22 1997

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Signature of Approving Official:

Date:

SFP 22 1997

deso

September 4, 1997

Steven R. Spaulding

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20480.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling;
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, e distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only.

 Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and eddress shown in your application is the person or firm to whom the registration will be issued. If you ere acting in behalf of another perty, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 8. EPA Use Only.

[Optional text]

ZOECON RF-342

EMULSIFIABLE CONCENTRATE FOR TOBACCO

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth]

An Insect Growth Regulator for the Control of
Insect Pests in Tobacco Processing and Storage Facilities

ACTIVE INGREDIENT:

(\underline{S}) -Methoprene [Isopropyl (2 \underline{E} ,4 \underline{E} ,7 \underline{S})-	
11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]:	33.6%
INERT INGREDIENTS:	66.4%
Total:	100.0%

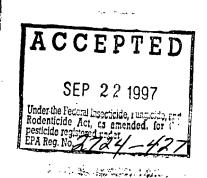
This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements.

NET CONTENTS:



INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects.

Almond moth (Ephestia cautella)
Cigarette beetle (Lasioderma serricorne)
Sawtooth grain beetle (Oryzaephilus surinamensis)
Red flour beetle (Tribolium castaneum)
Tobacco moth (Ephestia elutella)
Indian meal moth (Plodia interpunctella)
Lesser grain borer (Rhyzopertha dominica)
Merchant grain beetle (Oryzaephilus mercator)
Confused flour beetle (Tribolium confusum)
Warehouse beetle (Trogoderma spp.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Harmful if inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of rinsate or equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS; Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in area where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

STORAGE and DISPOSAL: Storage - Store in a cool, dry place. Pesticide Disposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Wellmark International Bensenville IL 60106

EPA Reg. No. 2724-427 Made in USA EPA Est. No.:

For information, call 1-800-XXX-XXXX.

[Optional text]

ZOECON RF-342 EMULSIFIABLE CONCENTRATE FOR TOBACCO

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth]

An Insect Growth Regulator for the Control of
Insect Pests in Tobacco Processing and Storage Facilities

ACTIVE INGREDIENT:

(<u>S</u>)-Methoprene [Isopropyl (2 <u>E</u> ,4 <u>E</u> ,7 <u>S</u>)-	
11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]:	33.6%
INERT INGREDIENTS:	66.4%
Total:	100.0%

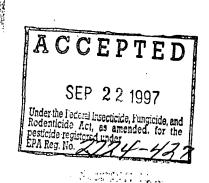
This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

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ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of rinsate or equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS; Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in area where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

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Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

STORAGE and DISPOSAL: Storage - Store in a cool, dry place. Pesticide Disposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Wellmark International Bensenville IL 60106

EPA Reg. No. 2724-427 Made in USA EPA Est. No.:

For information, call 1-800-XXX-XXXX.

[Optional text]

ZOECON RF-342 EMULSIFIABLE CONCENTRATE FOR TOBACCO

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth]

An Insect Growth Regulator for the Control of
Insect Pests in Tobacco Processing and Storage Facilities

ACTIVE INGREDIENT:

(<u>S</u>)-Methoprene [Isopropyl (2<u>E</u>,4<u>E</u>,7<u>S</u>)
11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]:

11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]:

133.6%

100.0%

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements.

NET CONTENTS:

SEP 2 7 1997
Under the Peccial Insection J.A. (1997)
Rodenticide Act, es amended of the pesticide registered under the Percent Park Reg. No. 27744-427

INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects.

Almond moth (Ephestia cautella)
Cigarette beetle (Lasioderma serricorne)
Sawtooth grain beetle (Oryzaephilus surinamensis)
Red flour beetle (Tribolium castaneum)
Tobacco moth (Ephestia elutella)
Indian meal moth (Plodia interpunctella)
Lesser grain borer (Rhyzopertha dominica)
Merchant grain beetle (Oryzaephilus mercator)
Confused flour beetle (Tribolium confusum)
Warehouse beetle (Trogoderma spp.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Harmful if inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of rinsate or equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS; Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in area where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

STORAGE and DISPOSAL: Storage - Store in a cool, dry place. Pesticide Disposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

WARRANTY AND CONDITIONS OF SALE

Seller makes no warranty, express or implied, concerning the use and handling of this product other than indicated on the label. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Wellmark International Bensenville IL 60106

EPA Reg. No. 2724-427 Made in USA EPA Est. No.:

For information, call 1-800-XXX-XXXX.

Зер	tember 5, 1997				
PRODUCT	STAMPED LABEL	NOMINAL*	PRN 96-6	NAME CHANGE	CSF
2724-401 Zoecon RF-299 RTU Carpet Pump Spray	last stamped label 12/16/91	meth. 0.007% to 0.010% permethrin 0.25% to 0.28% 9/97	NA	Submit 9/97	9/97
2724-420 Zoecon RF-329 Ant Growth Regulator	Don't have copy	4.8% to 4.9% 9/97	NA	Submit 9/97	9/97
2724-426 Zoecon RF-372 Collar	last stamped label 9/21/94	Yes	Submit 9/97	Submit 9/97	9/97
2724-427 Zoecon RF-342 Emulsifiable Concentrate for Tobacco (Dianex)	last stamped label 12/90	32.8% to 33.6% 9/97	NA	Submit 9/97	9/97
2724-441 Zoecon Methoprene Technical (RS)	last stamped label 4/5/93	90% to 94% 9/97	NA	Submit 9/97	9/97
2724-452 Apex 5E (RS)	last stamped label 6/1/94/WPS	65.7% to 67% 9/97	NA	Submit 9/97	9/97
2724-460 Zoecon 9207 Collar	last stamped label 4/5/94	2% to 2.1% 9/97	Submit 9/97	Submit 9/97	9/97
55947-94 NEW: 2724-477 Diacon (RS)	last stamped label 7/6/88	65.7% to 67% 9/97	NA	Submit 9/97	9/97
Reregistration - Recen	tly Approved - First Sub	omission			
2724-471 Methoprene/Chlorpyriphos Combination Collar for Dogs	3/10/97	Yes	Submit 9/97	Submit 9/97	9/97
2724-473 Altosid 10% Cattle Premix	5/5/97	Yes	NA	Submit 9/97	9/97

^{*} Values shown represent a change to nominal concentration for methoprene ai. Changes to other ai's are noted by name or abbreviation (PBO, permethrin)

SANDOZ AGRO, Inc. - Label Review Sheet

FILENAME:

L:\LABELS\CAHSPEC\

02724427\p342ECTA.97A

COVERSHEET UPDATE:

June 1997

PRODUCT:

ZOECON RF-342 EMULSIFIABLE

EPA REG. NO.:

2724-427

CONCENTRATE FOR

TOBACCO

APPROVED

SUPERSEDES:

OVERVIEW: LABEL SUBMITTED FOR METHOPRENE REREGISTRATION LABEL/NOMINAL/NAME CHANGE SANDOZ TO WELLMARK

Description of Major Changes
Added [Optional text] For Protection of Stored Tobacco (taken from marketing label) Changed ingredient statement to nominal
Updated Environmental Hazards Statement per rereg. doc.
Revised address, added information phone number and revised warranty from Zoecon to generic

[Optional text]

ZOECON RF-342 EMULSIFIABLE CONCENTRATE FOR TOBACCO

[For protection of stored tobacco from damage by Cigarette Beetle and Tobacco Moth]

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Storage Facilities

ACTIVE INGREDIENT:

 (S)-Methoprene [Isopropyl (2E,4E,7S)

 11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate]:
 32.833.6%

 INERT INGREDIENTS:
 67.266.4%

 Total:
 100.0%

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements.

NET CONTENTS:

INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects.

Almond moth (Ephestia cautella)
Cigarette beetle (Lasioderma serricome)
Sawtooth grain beetle (Oryzaephilus surinamensis)
Red flour beetle (Tribolium castaneum)
Tobacco moth (Ephestia elutella)
Indian meal moth (Plodia interpunctella)
Lesser grain borer (Rhyzopertha dominica)
Merchant grain beetle (Oryzaephilus mercator)
Confused flour beetle (Tribolium confusum)
Warehouse beetle (Trogoderma spp.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Harmful if inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if imitation persists.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of rinsate or equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS; Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in area where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

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Mixing Instructions: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

STORAGE and DISPOSAL: Storage - Store in a cool, dry place. Pesticide Disposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.

WARRANTY AND CONDITIONS OF SALE

Zoecon Corporation Seller makes no warrantys, express or implied, concerning the use and handling of that this product conforms to the chemical description other than indicated on the label, and is useful for the control of insect pests as described herein. Neither Zoecon nor the seller makes any other warranty, express or implied. Buyer assumes all risks of use and handling of this material when such use and handling are contrary to label instructions.

Zoecon Corporation
A Sandoz Company
12200 Denton Drive, Dallas, Texas 75234
Wellmark International
Bensenville IL 60106

EPA Reg. No. 2724-427 Made in USA EPA Est. No.:

For information, call 1-800-XXX-XXXX

Page 218 - *Confidential Statement of Formula may be entitled to confidential treatment*		



United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460

Registration Amendment

OPP Identifier Number

	App	pilcation	for Pestic	iae:	X O	ther	1	56413
		S	ection I					
. Company/Product Number	er	T. 2 777		PA Product Mar	-		3. Proposed	Classification
2724-427				Phil Hutton			D Particle 1	
. Company/Product (Name)		PM#			75,211	X None	Restricted	
Zoecon RF-342 Emulsifiable Concentrate			ate	18				
Zoecon Corporat A Sandoz Compan 12200 Denton Dr Dallas TX 752 Check if this	ion y ive	Code)	(b)(i to:					Section 3(c)(3) tion and labeling
		Se	ction I I	CANCEL TO				7.7.5.93
Amendment - Explain below Resubmission in response to Agency letter dated Notification - Explain below.			. X	Final printed labels in response to Agency letter dated "Me Too" Application. y Other - explain below.				
Appilea	tion for Rere	gistrati	on	掘			3.1	
		Sect	ion III				7-1	
. Material This Product W	/III Be Packaged In:			3.0140				
Child-Resistant Packaging	Unit Packaging	11,74.7	Water Solub	le Packaging	2	. Type of Co	ntainer	
Yes*	Yes No		Yes X No			X PI	etal astic ass	
* Certification must be submitted.	If "Yes," Unit Package wgt.	No. per container	If "Yes,"	No. p		Pa	aper ther (Specify)_	
3. Location of Net Contents	Information	4. Size(s) o	f Retail Containe	er	5. Loc	ation of Label	Directions	
	ontainer	1 07 -	128 oz.	1/24/75	X	On Labeling	accompanying	nroduct
6. Manner In Which Label Is		X Litho	ograph er glued ciled	Othe	r (OII Laboring	accompanym)
			ction IV		7/		M1. 0	
1. Contact Point (Complete	items directly below	for identificati		o be contacted,	if neces			(A) (D)
Name Kelly J	. Parker		Title	gulatory S	pecia	0.00	214/888	Area Code
I certify that the statemen I acknowledge that any k both under applicable law	nowingly false or mis	Certifications form and all sleading states	attachments the	preto are true, a nishable by fine	ccurate a	and complete, isonment or	Red	e Application eived Stamped)
2. Signature	of Park	er	3. Title	julatory S	pecia	list		
1. Typed Name	U .		5. Date				1	
Kelly J	. Parker	10	20	November	1991			219

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any data submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper or a mockup of the proposed label. If prepared as a mockup, it should be constructed in such a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission. Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

<u>SECTION I</u> - This section must be completed, as applicable, for all registration actions.

- 1. Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a <u>specific</u> <u>EPA-registered product</u>. This section is <u>not to</u> be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate page if additional space is needed.

SECTION *111 (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.

 2. Type of Retail Container - Indicate type of container in which product will be marketed.
- 3. Location of Met Contents Specify the net contents of all retail containers for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions Indicate the location of the use directions for your product.
 6. Manner in which label is affixed to product Indicate the method product label is attached to retail container.

SECTION IY (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new ື່ກໍ່ຕັ້ວນີ້ມີຮູ້ts registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

(A)	9	E	P	Δ

United States Environmental Protection Agency Office of Pesticide Programs (H7505C) Washington, DC 20460

	Registration
54	Amendment
Y	Other

OPP Identifier Number

Application for Pe	sticide:				
Section I					
Company/Product Number	EPA Product Manager Reproduct Manager Reproduct Manager				
2724-427	Phil Hutton				
4. Company/Product (Name)	PM# None Restricted				
Zoecon RF-342 Emulsifiable Concentrate	18				
5. Name and Address of Applicant (Include ZIP Code) Zoecon Corporation A Sandoz Company 12200 Denton Drive Dallas TX 75234 Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name				
Section II					
	Final printed labels in response to				
Amendment - Explain below	Agency letter dated				
Resubmission in response to Agency letter dated	"Me Too" Application.				
Notification - Explain below.					
	Other - explain below.				
Explanation: Use additional page(s) if necessary. (For section I and Section II a	ection II.)				
Application for Reregistration	Application for Reregistration				
Section III	The state of the s				
Material This Product Will Be Packaged In:					
	Soluble Packaging 2. Type of Container				
Yes* Yes	Yes Metal Plastic				
X No X No	No X Glass				
Commodition made by	Paper Other (Specify) container				
3. Location of Net Contents Information 4. Size(s) of Retail Co	ontainer 5. Location of Label Directions				
	On Label				
6. Manner In Which Label Is Affixed To Product Lithograph					
Paper gluedOther					
Stenciled Section IV					
Section IV 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Title	Telephone No. (luclude Area Code)				
Kelly J. Parker	Regulatory Specialist 214/888 272				
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					
2. Signature / 3. Title					
Kelly J. Parker	Regulatory Specialist				
4. Typed Name 5. Date	tt.				
Kelly J. Parker	20 November 1991 221				

PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

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4. Five copies of draft labeling;

5. Three copies of any data submitted;

6. Authorization letter where applicable;

7. Matrices where applicable.

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SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

SECTION I - This section must be completed, as applicable, for all registration actions.

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- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.

3. Proposed Classification - Specify the proposed classification of this product.

4. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

5. Name and Address of Applicant - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Expedited Review - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; general label revision of use directions." Attach a separate bage if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. Type of Packaging - Check the appropriate block if your product will be packaged in the indicated packaging types.

- Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contents Specify the net contents of all retail containers for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.

 5. Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner, in which laber is affixed to product Indicate the method product label is attached to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc. 1-5. Self-explanatory.

6. EPA Use Only.

U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

ZOECON INDUSTRIES, INC. 12200 DENTON DRIVE DALLAS, TX 75234

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 11/25/91. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

20 November 1991

Mr. Willie Nelson
Product Management Team (18)
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall, Bldg. 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

RE: Methoprene Reregistration, List A - Case 0030

Dear Mr. Nelson:

Enclosed in quadruplicate are data in support of reregistration of the subject products containing methoprene as the active ingredient. Please disregard suffixes in the code names for products. Those are strictly internal designations.

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 Product Specific ID# 2724-RD-7

MRID Number	Study
	Wilkins, C. Storage Stability of Methoprene EC 65% (RF 174) EPA Reg. No. 2724-286, 2724-405, 55947-88, 55947-94. Zoecon Study Number 1747. Unpublished. 22 pages.
	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 337, "Determination of Methoprene in RF 174 by Gas Chromatography Analysis"</u> . Zoecon Study Number 1539. Unpublished. 16 pages.
	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J., Color, Physical State, Odor, Specific Gravity, pH, Flashpoint, and Viscosity of RF 174, EPA Registration Numbers 2724-286, 2724-405, 55947-88 and 55947-94. Zoccon Study Number 1758. Unpublished. 23 pages.
	Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC: Acute Oral Toxicity Study in Male and Female Rats . SRI Study No. LSC 2673-M027-91. Zoecon Study No. 1728. Unpublished. 41 pages.
·	Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R174 SAN 300 I 66EC: Primary Skin Irritation Study in Rabbits. SRI Study No. LSC 2673-M029-91. Zoecon Study No. 1730. Unpublished. 40 pages.

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	Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC: Eye Irritation Study in Rabbits. SRI Study No. LSC 2673-M030-91. Zoecon Study No. 1731. Unpublished. 42 pages.
	Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC: Acute Dermal Toxicity Study in Male and Female Rabbits . SRI Study No. LSC 2673-M028-91. Zoecon Study No. 1729. Unpublished. 39 pages.
	Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R174 SAN 800 I 66EC: Skin Sensitization Study in Guinea Pigs . SRI Study No. LSC 2673-M031-91. Zoecon Study No. 1732. Unpublished. 60 pages.
	data are also being submitted in support of Diacon, EPA Reg. No. 55947-94, Product our sister company, Sandoz Crop Protection Corporation.
Apex 5E, EPA Reg. Product Specific ID	
formulations are ident agent of Sandoz Crop	1728, 1729, 1730, 1731, 1732, 1747, 1758 are all applicable to this product. The ical, the registered use sites are different. A letter certifying Zoecon Corporation as an Protection Corporation, is being provided under separate cover. As their agent, we are ata in support of the Apex 5E registration currently being transferred to Zoecon.
Zoecon RF-274 Foo Product Specific ID	gger, EPA Reg. No. 2724-337 # 2724-RD-22
MRID Number	Study
	Wilkins, C. <u>Stability of (S)-Methoprene/Permethrin Solvent Based Fogger/Aerosol</u> (RF274B) EPA Reg. No. 2724-337. Zoecon Study Number 1301. Unpublished. 14 pages.
	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 63C, "Procedure for the Analysis of Permethrin and Methoprene in RF 274 and RF 280 (Solvent Based Foggers and Aerosols)"</u> . Zoecon Study Number 1539. Unpublished. 21 pages.
	Clark, A. Physical and Chemical Properties Testing for Zoecon RF-274 Fogger. MRI No. 9914-F. Zoecon No. 1672. Unpublished. 13 pages.
	McDaniel, J. <u>Flash Point Determination of Zoecon RF-274 Fogger Concentrate</u> . Zoecon Study Number 1680. Unpublished. 8 pages.
	Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R274B SAN 1139 I5.8AE Skin Sensitization Study in Guinea Pigs . SRI Study No. LSC 2673-M037-91. Zoecon Study No. 1738. Unpublished. 55 pages.
Zoecon RF-275 Pre Product Specific ID	essurized Spray, EPA Reg. No. 2724-338 # 2724-RD-23
MRID Number	Study
	Clark, A. Physical and Chemical Properties Testing for Zoecon RF-275 Pressurized Spray. MRI No. 9914-F. Zoecon No. 1674. Unpublished. 15 pages.
,	McDaniel, J. Flash Point Determination of Zoecon RF-275 Aerosol Concentrate. Zoecon Study Number 1680. Unpublished. 8 pages.
	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 324 "Procedure for the Analysis of Methoprene, Synergist MGK-264, Pyrethrins and PBO in a Water-Based System (Including RF 275)". Zoecon Study Number 1539. Unpublished. 19 pages.</u>

Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 Product Specific ID# 2724-RD-24 MRID Number Study Clark, A. Physical and Chemical Properties Testing for Zoecon RF-280 Aerosol. MRI No. 9914-F. Zoecon No. 1671. Unpublished. 13 pages. McDaniel, J. Flash Point Determination of Zoecon RF-280 Aerosol Concentrate. Zoecon Study Number 1680. Unpublished. 8 pages. Zoecon Study 1301, 1539, and 1738 listed above for Zoecon RF-274 Fogger are also applicable to this product. The only difference in the two products is a small difference in the amount of propellant. Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 Product Specific ID# 2724-RD-25 MRID Number Study Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 329, "Procedure for the Procedure For the Institute of the </u> Analysis for Methoprene in a Methoprene Emulsifiable Concentrate (RF 291)". Zoecon Study Number 1539. Unpublished. 16 pages. McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-291, EPA Registration Number 2724-352. Zoecon Study Number 1667. Unpublished. 23 pages. Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 Product Specific ID# 2724-RD-26 Wilkins, C. Storage Stability of Methoprene Bolus (RF 293) EPA Reg. No. 2724-356. Zoecon Study Number 1744. Unpublished. 19 pages. Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density of RF 293, EPA Registration Number 2724-356. Zoecon Study Number 1712. Unpublished. 17 pages. Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., Precision and Accuracy for Current Analytical Procedure (CAP) Number 223C, "Procedure for the Analysis of Methoprene in RF 293, (Methoprene Bolus)". Zoecon Study Number 1539. Unpublished. 16 pages. Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 Product Specific ID# 2724-RD-27

MRID Number	<u>Study</u>
	Wilkins, C. Storage Stability of (S)-Methoprene/Permethrin Water Based Aerosol (RF297A) EPA Reg. No. 2724-360. Zoecon Number 1308. Unpublished. 14 pages.
	Clark, A. Physical and Chemical Properties Testing for Zoecon RF-29/ Aerosol. MRI No. 9914-F. Zoecon No. 1673. Unpublished. 15 pages.
	McDaniel, J. Flash Point Determination of Zoecon RF-297 Aerosol Concentrate. Zoecon Study Number 1680. Unpublished. 9 pages.
	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 310 "Procedure for the Analysis of Water Based Aerosols Containing Permethrin and Methoprene (Including RF 297)". Zoecon Study Number 1539. Unpublished. 20 pages.</u>
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	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R297 ZOE 014I.47AE: Acute Oral Toxicity Study in Male and Female Rats</u> . SRI Study No. LSC 2561-M008-91. Zoecon Study No. 1675. Unpublished. 34 pages.
	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R297 ZOE 014I.47AE: Acute Dermal Toxicity Study in Male and Female Rabbits</u> . SRI Study No. LSC 2561-M009-91. Zoecon Study No. 1676. Unpublished. 43 pages.
	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R297 ZOE 014I.47AE: Primary Skin Irritation Study in Rabbits</u> . SRI Study No. LSC 2561-M010-91. Zoecon Study No. 1677. Unpublished. 42 pages.
	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R297 ZOE 0141.47AE: Primary Eye Irritation Study in Rabbits.</u> SRI Study No. LSC 2561-M011-91. Zoecon Study No. 1678. Unpublished. 44 pages.
	Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R297 ZOE 014I.47AE: Skin Sensitization Study in Guinea Pigs. SRI Study No. LSC 2561-M012-91. Zoecon Study No. 1679. Unpublished. 59 pages.
ALTOSID CP-10, El Product Specific ID	PA Reg. No. 2724-367 # 2724-RD-28
	Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density of RF 74, EPA Registration Number 2724-367. Zoecon Study Number 1712. Unpublished. 17 pages.
	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 77A, "Procedure for the Analysis of (R,S)-Methoprene in RF 74, (CP10)"</u> . Zoecon Study Number 1539. Unpublished. 16 pages.
Granular IGR Cattle Product Specific ID	s Supplement, EPA Reg. No. 2724-372 # 2724-RD-30
	Sheehan, T. Precision and Accuracy for Current Analytical Procedure (CAP) Number 335, "Procedure for the Analysis for (R,S)-Methoprene in Zoecon's Granular and Block Cattle Supplements EPA REG NOS 2724-372 and 2724-373". Zoecon Study Number 1721. Unpublished. 22 pages.
	Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density for 9118SAN800I0.02GB, Granular Feed Supplement, EPA Registration Number 2724-372. Zoecon Study Number 1726. Unpublished. 17 pages.
Block IGR Cattle Su Product Specific ID	applement, EPA Reg. No. 2724-373 # 2724-RD-31
MRID Number	Study
	Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density for 9119SAN800I0.02BB, Block Feed Supplement, EPA Registration Number 2724-373. Zoecon Study Number 1726. Unpublished. 17 pages.
	sted above for Granular IGR Cattle Supplement (EPA Reg. No. 2724 372) also provides of data for this cattle supplement product. The formulas are essentially identical.
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ALTOSID Briquets, EPA Reg. No. 2724-375 Product ID# 2724-RD-33

MRID Number	Study
,	Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, and Density of RF 433N, EPA Registration Number 2724-375</u> . Zoecon Study Number 1712. Unpublished. 17 pages.
	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 325, "Procedure for the Analysis of Methoprene in RF 433N (30 Day Briquet and Briquet Premix)"</u> . Zoecon Study Number 1539. Unpublished. 16 pages.
Kabat Tobacco Pro Product Specific II	otector, EPA Reg. No. 2724-377 D# 2724-RD-34
MRID Number	Study
	McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-385N, EPA Registration Number 2724-377</u> . Zoecon Study Number 1667. Unpublished. 23 pages.
·	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 321 "Determination of Methoprene in RF 385N and RF 386N (Kabat)"</u> . Zoecon Study Number 1539. Unpublished. 17 pages.
Kabat Protector C Product Specific II	oncentrate, EPA Reg. No. 2724-384 D# 2724-RD-36
MRID Number	Study
	McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-386N, EPA Registration Number 2724-384</u> . Zoecon Study Number 1667. Unpublished. 21 pages.
analytical method for	listed above for Kabat Tobacco Protector provides precision and accuracy data on the both products. These two products are identical except in the level of methoprene; the actor is 5% methoprene and the Concentrate product is 80% methoprene.
Altosid Liquid Lar Product Specific II	vicide, EPA Reg. No. 2724-392 D# 2724-41
MRID Number	Study
	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-438N, EPA Registration Number 2724-392. Zoecon Study Number 1667. Unpublished 24 pages.
	Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., Precision and Accuracy for Current Analytical Procedure (CAP) Number 328, "Procedure for the Analysis of (S)-Methoprene in RF 437N, RF438N and RF 329 (Altosid Liquid Larvicide SR-20, SR-5 and Pharorid)". Zoecon Study Number 1539. Unpublished, 23 pages.
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Altosid Liquid Larvicide Concentrate, EPA Reg. No. 2724-393 Product Specific ID# 2724-42

MRID Number	Study
	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of RF-437N, EPA Registration Numbers 2724-393 and 2724-446. Zoecon Study Number 1667. Unpublished. 24 pages.
····	Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R437N SAN 810 I20CS: Acute Oral Toxicity Study in Male and Female Rats. SRI Study No. LSC 2673-M032-91. Zoecon Study No. 1733. Unpublished. 36 pages.
	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Acute Dermal Toxicity Study in Male and Female Rabbits</u> . SRI Study No. LSC 2673-M033-91. Zoecon Study No. 1734. Unpublished. 41 pages.
	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS:</u> <u>Primary Skin Irritation Study in Rabbits</u> . SRI Study No. LSC 2673-M034-91. Zoecon Study No. 1735. Unpublished. 39 pages.
	Schindler, J.E., and Baldwin, R.C. <u>Zoecon Sample No. R437N SAN 810 I20CS: Eve Irritation Study in Rabbits</u> . SRI Study No. LSC 2673-M035-91. Zoecon Study No. 1736. Unpublished. 44 pages.
	Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R437N SAN 810 I20CS: Skin Sensitization Study in Guinea Pigs SRI Study No. LSC 2673-M036-91. Zoecon Study No. 1737. Unpublished. 54 pages.
Zoecon Study Number the analytical method	er 1539 listed above for Altosid Liquid Larvicide provides precision and accuracy data on I for both products.
Zoecon RF-299 RT Product Specific II	TU Carpet Pump Spray, EPA Reg. No. 2724-401 D# 2724-44
MRID Number	Study
	Wilkins, C. <u>Stability of (S)-Methoprene/Permthrin Pump Spray EPA Reg. No.</u> <u>2724-401</u> . Zoecon Study Number 1283. Unpublished. XX pages.
	McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. <u>Color</u> , <u>Physical State</u> , <u>Odor</u> , <u>Specific Gravity</u> , <u>pH</u> , <u>Flammability-Flashpoint</u> , and <u>Viscosity of RF-299</u> , <u>EPA Registration Number 2724-401</u> . Zoecon Study Number 1667. Unpublished. 23 pages.
	Lephart, J. Method Validation for the Analysis of (R,S)-Methoprene or (S)-Methoprene and Permethrin in a RTU Water-based Carpet Spray. Zoecon Project Code R299SAN1129I.26AL. 1303 Report-VMOA. Unpublished. 62 pages.
Zoecon RF-322 Or Product Specific II	Lephart, J. Method Validation for the Analysis of (R,S)-Methoprene or (S)-Methoprene and Permethrin in a RTU Water-based Carpet Spray. Zoecon Project Code R299SAN1129I.26AL. 1303 Report-VMOA. Unpublished. 62 pages.
	Lephart, J. Method Validation for the Analysis of (R,S)-Methoprene or (S)-Methoprene and Permethrin in a RTU Water-based Carpet Spray. Zoecon Project Code R299SAN1129I.26AL. 1303 Report-VMOA. Unpublished. 62 pages.
Product Specific II	Lephart, J. Method Validation for the Analysis of (R,S)-Methoprene or (S)-Methoprene and Permethrin in a RTU Water-based Carpet Spray. Zoecon Project Code R299SAN1129l.26AL. 1303 Report-VMOA. Unpublished. 62 pages. vicidal Pump Spray, EPA Reg. No. 2724-404 D# 2724-RD-46

McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of RF-322, EPA Registration Number 2724-404. Zoecon Study Number 1667. Unpublished. 23 pages. Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 Product Specific ID# 2724-RD-48 MRID Number Study McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, Flammability-Flashpoint, and Viscosity of RF-329, EPA Registration Number 2724-420. Zoecon Study Number 1667. Unpublished. 24 pages. Schindler, J.E., and Baldwin, R.C. Zoecon Sample No. R329 SAN 810 I4.8CB: Skin Sensitization Study in Guinea Pigs . SRI Study No. LSC 2673-M038-91. Zoecon Study No. 1739. Unpublished. 56 pages. Zoecon Study 1539 listed above for ALTOSID Liquid Larvicide, EPA Reg. No. 2724-392 is also applicable to this product as they are essentially identical formulations. Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 Product Specific ID# 2724-RD-49 MRID Number Study Moorman, R., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, and Density of RF 292A, EPA Registration Number 2724-421. Zoecon Study Number 1712. Unpublished. 17 pages. Nguyen, K. Method for the Assay of S-Methoprene in Briquets. Zoecon Study TR-1275. Unpublished. 70 pages. Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 Product Specific ID# 2724-RD-50 MRID Number Study Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., Precision and Accuracy for Current Analytical Procedure (CAP) Number 330, "Procedure for the Analysis for Methoprene in RF 342 (Dianex)". Zoecon Study Number 1539. Unpublished. 16 pages. McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J. Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of RF-342, EPA Registration Number 2724-427. Zoecon Study Number 1667. Unpublished. 23 pages. Methoprene Technical, EPA Reg. No. 2724-441 Product Specific ID# 2724-RD-56 MRID Number Study McDaniel, J., Moorman, R., Nguyen, K., Thornton, K., Sheehan, T., Lephart, J.; Color, Physical State, Odor, Specific Gravity, pH, Flammability-Flashpoint, and Viscosity of

(R,S)-Methoprene, EPA Registration Number 2724-441. Zoecon Study Number 1669.

Unpublished. 21 pages.

Moorman, R., Thornton, K., Nguyen K., Sheehan, T., Lephart, J., <u>Precision and Accuracy for Current Analytical Procedure (CAP) Number 284, "Procedure for The Analysis of Technical Methoprene (EPA Registration Numbers 2724-441 and 2724-442)"</u>. Zoecon Study Number 1539. Unpublished. 17 pages.

(S)-Methoprene Technical, EPA Reg. No. 2724-442 Product Specific ID# 2724-RD-51

MRID Number

Study

McDaniel, J., Moorman, R., Thornton, K., Sheehan, T., Lephart, J. <u>Color, Physical State, Odor, Specific Gravity</u>, pH, Flammability-Flashpoint, and Viscosity of (S)<u>Methoprene, EPA Registration Number 2724-442</u>. Zoecon Study Number 1669.
Unpublished. 21 pages.

Zoecon Study 1539 listed above for Methoprene Technical also provides precision and accuracy data for the current analytical procedure for S-Methoprene Technical.

Zoecon RF-437 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 Product Specific ID# 2724-RD-439

Zoecon Studies 1667, 1733, 1734, 1735, 1736, 1737 listed above for ALTOSID Liquid Larvicide Concentrate are also applicable to this product, since their formulations are identical. The only difference in the two products is in their labels; ALTOSID Liquid Larvicide is a manufacturing-use product and RF-437 carries an end-use label.

Zoecon Study 1539 listed above for ALTOSID Liquid Larvicide, EPA Reg. No. 2724-392 is also applicable to this product as they are essentially identical formulations.

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 Product Specific ID# 2724-RD-52

MRID Number	<u>Study</u>
	Nguyen, K. Method Validation for the Analysis of (S)-Methoprene in Altosid Pellets and Premix. Zoecon Project Code R330SAN810I4XX. 1413 Report-VMOA. Unpublished 34 pages.
	Schweitzer, M. <u>Product Chemistry of Altosid Pellets</u> . Battelle Study Number SC900157 Zoecon Study Number 1565. Unpublished. 24 pages.

Best regards,

Kelly J. Parker Regulatory Specialist

800/527-0512

11/20

Zoecon Corporation

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

25 November 1991

Mr. Phil Hutton
Product Manager 18
Insecticide-Rodenticide Branch
Office of Pesticide Programs (H7504C)
Document Processing Desk (6(a)(2))
Room 266A, Crystal Mall 2
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Adverse Effects Discovered In Toxicology Data

Dear Mr. Hutton:

The following studies were submitted in accordance with the R.E.D. for Methoprene. These studies had surprising results; hence, considered by EPA to be adverse effects. Please note that we have not seen confirmation of these results from product use in the marketplace.

Schindler, J.E. and Baldwin, R.C. <u>Zoecon Sample No. R174 SAN 800 I 66EC:</u>
<u>Primary Skin Irritation Study in Rabbits.</u> SRI Study No. LSC 2673-M029-91.

Zoecon Study No. 1730. Unpublished. 40 Pages. (See note 1.)

Results:

The 72-hour mean irritation score was 1.0 placing this product in Tox Category IV; however, 2 rabbits showed irritation through 21 days after patch removal.

Schindler, J.E. and Baldwin, R.C. <u>Zoecon Sample No. R174 SAN 800 I 66EC: Skin Sensitization Study In Guinea Pigs.</u> SRI Study No. LSC 2673-M031-91. Zoecon Study No. 1732. Unpublished. 60 Pages. (See note 1.)

Resutts:

This study showed a positive response.

Schindler, J.E. and Baldwin, R.C. <u>Zoecon Sample No. R297 ZOE 0141': 17'AE Primary Skin Irritation Study in Rabbits</u>. SRI Study No. LSC 2561-M010-91... Zoecon Study No. 1677. Unpublished. 42 Pages. (See note 2.)

Results:

The 72-hour mean irritation score was 3.8 placing this product in Tox Category III; however, 2 rabbits showed

irritation to 21 days after patch removal.

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Schindler, J.E. and Baldwin, R.C. Zoecon Sample No. R437N SAN 810 L20CS: Skin Sensitization Study in Guinea Pigs. SRI International. SRI Study No. LSC 2673-M036-91. Zoecon Study No. 1737. Unpublished. 54 Pages. (See note 3.)

Results:

This study showed a positive response.

Notes:

- Zoecon Sample No. R174 SAN 800 I 66EC is the test material code for EPA Registration Numbers 2724-286 and 55947-88 (Under separate cover, Sandoz Crop Protection Corporation has certified Zoecon Corporation as their agent for this product pending transfer completion).
- 2. Zoecon Sample No. R297 ZOE 014 I .47 AE is the test material code for EPA Registration Number 2724-360.
- Zoecon Sample No. R437N SAN 810 I 20CS is the test material code for EPA Registration Numbers 2724-393, and 2724-446.

Best regards,

Kelly J. Parker

Regulatory Specialist -

800/527-0512

XC with Data:

Mr. Gary Sprock

Registration Specialist

Department of Pesticide Regulation

California Environmental Protection Agency

1220 N Street

Sacramento, CA 95814

ZOECON RF-342 EMULSIFIABLE CONCENTRATE FOR TOBACCO

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Storage Facilities

ACTIVE INGREDIENTS:

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements.

NET CONTENTS:





INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects.

Almond moth (Ephestia cautella)
Cigarette beetle (Lasioderma serricorne)
Sawtooth grain beetle (Cryzaephilus surinamensis)
Red flour beetle (Tribolium castaneum)
Tobacco moth (Ephestia elutella)
Indian meal moth (Plodia interpunctella)
Lesser grain borer (Rhyzopertha dominica)
Merchant grain beetle (Cryzaephilus mercator)
Confused flour beetle (Tribolium confusum)
Warehouse beetle (Trogoderma spp.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Harmful if inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS; Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1,000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in area where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

STORAGE & DISPOSAL: Storage - Store in a cool, dry place. Pesticide Disposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by buring. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

WARRANTY AND CONDITIONS OF SALE

Zoecon Corporation warrants that this product conforms to the chemcial description on the label and is useful for the control of insect pests as described herein. Neither Zoecon nor the seller makes any other warranty, express or implied.

Zoecon Corporation A Sandoz Company 12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-427 1091-8:0150E;RED EPA Est. 55947-CA-1 Made in USA © 1988 Zoecon

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

10 May 1991

Mr. Willie Nelson Product Management Team 18 U.S. Environmental Protection Agency Document Processing Desk (RED/RD-0030) Office of Pesticide Programs (H7504C) Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202

RE:

Request for an Extension of Inhalation Toxicology Data

Request for a Meeting

Product Specific ID# 2724-RD-50

EPA Reg. No. 2724-427

Dear Mr. Nelson:

Zoecon Corporation respectfully requests an extension for submission of inhalation toxicology data for the subject product. Further, we would like to meet with individuals within SRRD, RD and HED of EPA who can authorize policy changes with respect to inhalation toxicology.

First of all, the EPA appears to be taking a hard stand on the tox grouping of methoprene products. What was acceptable to the Agency even three years ago appears not acceptable today...especially accepting ($\underline{R},\underline{S}$)-Methoprene data as relevant to (\underline{S})-Methoprene data.

Secondly, we don't understand the absurdness of the required inhalation studies, both what is required to be tested and, most absurd, how it is to be tested. The limit test which meets current guidelines of 5 mg test material/L of air is impossible to achieve when trying to comply with the SEP which requires that at least 25% of the particles must have a MMAD $\leq 1~\mu$. The two "requirements" are mutually exclusive. One laboratory has told us that to achieve both requirements, they do two separate limit tests and hope that EPA can merge the results. This means that the lab requires the sponsor to provide a minimum of 5 kg of test material, as 95% of it will be wasted trying to generate such small particles, as well as obtaining maximum chamber concentrations.

Thirdly, these requirements are cost prohibitive. To generate 5 kg of test material (only for an inhalation toxicology study), could require an unscheduled production run for the active ingredient and/or the end-products. (§)-Methoprene is one of the most expensive active ingredients to manufacture. Two limit studies to reach one conclusion is also costly (our estimate is \$10,000 per limit study, assuming only animal exposure and reduced particle size generation by the laboratory). Analytical costs should also be included in this estimate; however, Zoecon has traditionally conducted the analytical work in-house.

Finally, these requirements are also time prohibitive. The limiting factors include 1) amount of test material required, 2) the chemist's time required to characterize beginning material, to validate the method, and to analyze the chamber samples, 3) laboratory availability (frequently scheduling is required months in advance). Because of the analytical burden of the RED for the product chemistry portion, the analytical work for the inhalation toxicology may be conducted at the inhalation laboratory. This would further increase the time necessary to conduct inhalation studies. All inhalation studies would be conducted at the same laboratory to negate the need for duplicative analytical work. To get on a laboratory master schedule to conduct several studies at once would automatically put us in violation of the 21 November 1991 deadline.

Zoecon requests the time of submission be contingent upon how long it takes EPA to resolve these policy issues. The Society of Toxicology is currently working as a group to suggest changes to this policy; therefore, it seems that this is not only a Zoecon request for a change, but a science- and industry-wide request. We would be happy to set up a room at our hotel to meet with Agency officials. Please let me know when you can schedule this meeting and also if our extension has been granted.

Best regards,

Kelly J. Parker

Regulatory Specialist

800/527-0512

CC:

Anne Lindsay, RD, EPA Phil Hutton, RD, EPA

Kelly of Parker

Karen Samek, SRRD, EPA

Dr. Penelope Fenner-Crisp, HED, EPA

Dr. Reto Engler, HED, EPA

Dr. Judith Graham, R&D, EPA (Research Triangle)

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

10 May 1991

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE:

Request for an Extension of Inhalation Toxicology Data

Request for a Meeting

Product Specific ID# 2724-RD-50

EPA Reg. No. 2724-427

Dear Mr. Nelson:

Zoecon Corporation respectfully requests an extension for submission of inhalation toxicology data for the subject product. Further, we would like to meet with individuals within SRRD, RD and HED of EPA who can authorize policy changes with respect to inhalation toxicology.

First of all, the EPA appears to be taking a hard stand on the tox grouping of methoprene products. What was acceptable to the Agency even three years ago appears not acceptable today...especially accepting $(\underline{R},\underline{S})$ -Methoprene data as relevant to (\underline{S}) -Methoprene data.

Secondly, we don't understand the absurdness of the required inhalation studies, both what is required to be tested and, most absurd, how it is to be tested. The limit test which meets current guidelines of 5 mg test material/L of air is impossible to achieve when trying to comply with the SEP which requires that at least 25% of the particles must have a MMAD $\leq 1~\mu$. The two "requirements" are mutually exclusive. One laboratory has told us that to achieve both requirements, they do two separate limit tests and hope that EPA can merge the results. This means that the lab requires the sponsor to provide a minimum of 5 kg of test material, as 95% of it will be wasted trying to generate such small particles, as well as obtaining maximum chamber concentrations.

A SANDOZ Company
12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

10 May 1991

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE:

Request for an Extension of Inhalation Toxicology Data

Request for a Meeting

Product Specific ID# 2724-RD-34

EPA Reg. No. 2724-377

Dear Mr. Nelson:

Zoecon Corporation respectfully requests an extension for submission of inhalation toxicology data for the subject product. Further, we would like to meet with individuals within SRRD, RD and HED of EPA who can authorize policy changes with respect to inhalation toxicology.

First of all, the EPA appears to be taking a hard stand on the tox grouping of methoprene products. What was acceptable to the Agency even three years ago appears not acceptable today...especially accepting ($\underline{R},\underline{S}$)-Methoprene data as relevant to (\underline{S})-Methoprene data.

Secondly, we don't understand the absurdness of the required inhalation studies, both what is required to be tested and, most absurd, how it is to be tested. The limit test which meets current guidelines of 5 mg test material/L of air is impossible to achieve when trying to comply with the SEP which requires that at least 25% of the particles must have a MMAD ≤ 1 μ. The two "requirements" are mutually exclusive. One laboratory has told us that to achieve both requirements, they do two separate limit tests and hope that EPA can merge the results. This means that the lab requires the sponsor to provide a minimum of 5 kg of test material, as 95% of it will be wasted trying to generate such small particles, as well as obtaining maximum chamber concentrations.

Thirdly, these requirements are cost prohibitive. To generate 5 kg of test material (only for an inhalation toxicology study), could require an unscheduled production run for the active ingredient and/or the end-products. (S)-Methoprene is one of the most expensive active ingredients to manufacture. Two limit studies to reach one conclusion is also costly (our estimate is \$10,000 per limit study, assuming only animal exposure and reduced particle size generation by the laboratory). Analytical costs should also be included in this estimate; however, Zoecon has traditionally conducted the analytical work in-house.

Finally, these requirements are also time prohibitive. The limiting factors include 1) amount of test material required, 2) the chemist's time required to characterize beginning material, to validate the method, and to analyze the chamber samples, 3) laboratory availability (frequently scheduling is required months in advance). Because of the analytical burden of the RED for the product chemistry portion, the analytical work for the inhalation toxicology may be conducted at the inhalation laboratory. This would further increase the time necessary to conduct inhalation studies. All inhalation studies would be conducted at the same laboratory to negate the need for duplicative analytical work. To get on a laboratory master schedule to conduct several studies at once would automatically put us in violation of the 21 November 1991 deadline.

Zoecon requests the time of submission be contingent upon how long it takes EPA to resolve these policy issues. The Society of Toxicology is currently working as a group to suggest changes to this policy; therefore, it seems that this is not only a Zoecon request for a change, but a science- and industry-wide request. We would be happy to set up a room at our hotel to meet with Agency officials. Please let me know when you can schedule this meeting and also if our extension has been granted.

Best regards,

Kelly J. Parker

Regulatory Specialist

800/527-0512

CC: Anne Lindsay, RD, EPA

Kelly of Parker

Phil Hutton, RD, EPA

Karen Samek, SRRD, EPA

Dr. Penelope Fenner-Crisp, HED, EPA

Dr. Reto Engler, HED, EPA

Dr. Judith Graham, R&D, EPA (Research Triangle)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

JAN 2 | 1992

Ms. Kelly Parker Regulatory Specialist Zoecon Corporation A Sandoz Company 12200 Denton Drive Dallas, TX 75234

Dear Ms. Parker:

Subject: Request for an Extension for Storage Stability Data To Be Submitted to the Agency and Product Chemistry Guideline 151B-17(1)

(See the enclosed list of products covered)

Your Submission Dated July 1, 1991

This letter is in response to your letter of the above date submitted in support of the subject products. Under Section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended in 1988, which requires that the Agency reregister pesticides that were first registered before November 1, 1984. Pursuant to this Act, and your response to RED issued under the Provisions of this Act, we have reviewed your submission(s)/ request(s) and our conclusions are as follows:

- Your request for an extension of time to complete a 1 year storage stability study is unnecessary, since the Agency has established a policy in December 1991 to treat this data requirement much as it treats efficacy data requirements. The study is to be done and maintained in the registrants files, but not submitted to the Agency unless the Agency specifically calls for the study at some future time.

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

Product Chemistry Data Requirements

The following studies are <u>not</u> required for the products listed in the attachment; these studies are needed <u>only</u> for the Technical Grade of the Active Ingredient which have been received by the Agency.

- ° Solubility
- ° Melting Point
- ° Discussion of Formation of Impurities
- ° Boiling Point
- ° Octanol/Water Partition Coefficient
- ° Stability
- ° Analysis of Samples
- ° Vapor Pressure.

Miscibility-Data are required only if the emulsifiable liquid is intended to be diluted with petroleum solvents, but these products are not intended to be used with petroleum solvent; therefore, the data are not required.

Your request to amend your labeling to include the statement, "Breaks the flea life cycle," submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable, and a stamped copy is enclosed for your records. This stamped label does not constitute reregistration. The RED requirements are yet to be satisfied for that purpose.

Also, the Agency has no objection to the use of the Alternate Trademark "VIGREN" for your private labels instead of PRECOR which will be the trademark for your general product labelings.

Should you need further assistance, please contact Mr(s). Phil Hutton or Willie Nelson, PM Team 18, at (703) 305-6601.

Sincerely,

Anne E. Lindsay, Director

Registration Division

Office of Pesticide Program

STATUS OF METHOPRENE STANDARD

Request for a Waiver of Product Performance Data: 7/7/91
 Case Number and Name: 0030 Methoprene

EPA REG. NO.'s

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson Product Management Team 18 U.S. Environmental Protection Agency Document Processing Desk (RED/RD-0030) Office of Pesticide Programs (H7504C) Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202

RE:

Request for a Waiver of Product Performance Data Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of product performance data for the products listed below.

The requirement as listed in the Methoprene RED states that Guideline 95-10(b)(1): product performance for mosquitoes in cesspools, septic tanks, and waste treatment settling ponds should be followed. These products are not and have never been mosquito control products. These sites do not appear on the labels; therefore, we request a waiver of the product performance data.

EPA Reg. No.	Product Specific ID#	
2724-286 2724-337 2724-338 2724-339 2724-352 2724-356 2724-360 2724-367 2724-368 2724-372 2724-373 2724-373	2724-RD-7 2724-RD-22 2724-RD-23 2724-RD-24 2724-RD-25 2724-RD-26 2724-RD-27 2724-RD-28 2724-RD-29 2724-RD-30 2724-RD-31 2724-RD-31	

EPA Reg. No. Cont'd.

•	2724-384 2724-401	
	2/24-401	
	2724-404	
١	2724-420	
•	2724-427	
•	2724-441	
*	2724-442	

Product Specific ID# Cont'd.

Best regards,

Kelly J. Parker Regulatory Specialist 800/527-0512

CC: Phil Hutton, RD, EPA Dick King, SRRD, EPA

		PRODUCT CHEMISTRY REVIEW
		Duna Skapais P
		FROM: Reviewer: NDIRA CTAIRDLA Date: 1114 91
EPA REG	. NO.	FROM: Reviewer: NDIRA CTAIRDLA Date: 11/14/91 : 2724 - 27 PRODUCT NAME: LOC CON RF - 342 Emulsifiable Concentrate
		(oncentrate
FOOD US	E ()	<pre>INERTS CLEARED: C (), D (), E () NON FOOD USE () 170-199: () TOXIC INERTS LIST 1(), 2()</pre>
Please p	provi	de the requested information for the following checked items:
1. []	sub	mit the product specific product chemistry data for your product. [] If mitted earlier, provide MRID Number(s). [] Your product is not sufficiently ilar to the product you referenced.
	refer Lowin	ence to the Confidential Statement of Formula (CSF), please provide the g:
[]	a)	pH of product or pH at a specified water dilution.
[]	b)	Density of product.
[]	c)	Flash point of product.
[]	d)	Flash point of product with propellent as per item $\#6(q)$ or item $\#5(c)$.
[]	e)	Flame extension of product including flashbacks if noted.
[]	f)	The upper and lower certified limits based on the pure active ingredients rather than the technical or concentrate. Note that the lower limit of the active ingredients must be the same as the label claim in pure active form.
[]	g)	The upper and lower certified limits of the individually added inerts.
[]	h)	
[1]	i)	(d)
[]	ίţ	
		ed on the current CSF dated, your product will not meet label claim for the active ingredient. Please revise the label or the CSF so t the information agrees.
Uha ai	nnli	on the requested for the warver of corbain P.C. data
The s	sam	and has requested for the warver of cortain P.C. data e will be discussed on the following page + Justification
for a	Jran	extention of time for Storage Stability (year date on Chracteristics: provided to a penod of 18 months granted or approved to a penod of 18 months
Ast)er	extention of time for Storage Stability ()
nd Com	2/8/10	on Chracter 18tics, ved to a penod of 18 months
may	NE	246

PRODUCT CHEMISTRY REVIEW (cont'd)

4. []	Provide the chemical	identity	of all	components,	the	percenta	ge compo	sition, CAS
	Registry Number, and	Material	Safety	Data Sheet	(two	copies)	for the	following
٠	compounds:							

1.

2.

3.

4.

5.

The supplier may contact EPA directly referencing the File Symbol or EPA... Registration Number in their response. For dyes, provide the color index and CAS Registry Numbers for all components. For perfumes and flavorings, provide for each component in the mixture: the chemical name, CAS Registry Number, and the percentage or range in percentage in the mixture. Certify that flavors are non-food type. The confidential information submitted by the suppliers is kept confidential under FIFRA Section 10.

5. In the proposed labeling, provide the following information:

- [] a) Update the label Storage and Pesticide and Container Disposal Statements in accordance with [] PR Notice 84-1 for non-aerosol containers for houses and institutional uses or [] PR Notice 83-3 for all other uses.
- { } b) Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement per 40 CFR 156.10(h) (2) (iii).
- [] c) Under the heading PHYSICAL OR CHEMICAL HAZARDS, list the product as Extremely Flammable (because your product contains flammable propellents).
- [] d) Provided that the solvent does not have insecticidal activity, it should be removed from the ingredient statement active ingredient listing and the percentage added to the inert ingredients. If the solvent has insecticidal properties, provide the EPA Registration Number.
- { } e) Add a footnote to the inert ingredients indicating: Contains aromatic petroleum distillates, xylene or xylene-range aromatic solvent.
- [] f) Since your data matrix does not provide a dielectrical breakdown voltage, you must add the following statement to the Physical or Chemical Hazards heading:

Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Stability request & warver is granted so this is an EP at requirement is only for TGAI Flammability is N/A strice this is a solid it does not contain any PH. Waiver is granted some this is N/A because its a solid Miscibility Warver is granted since this is applicable for only but-not emulsifiable licepteds, when deluted with oils, though this italiqued with oil. Oct Mater Partition Co-efficient Data is not recognited for end use products so warver is granted. Marver for V.P. is granted + is only Napor l'ressure recymrel for the technical & Discussion of Fermation of Impurities Waiver for this is also.
Granted, since the same is required only of a Technical active d'agreclient. Solubility Keywest for waiver is granted since this applies to Vilacien is granted since this is an EP Molling Pourt Melting Poul Mainer is grouted " " Alredysis of Samples ... "

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE:

Request for a Waiver of Melting Point

All Products Listed in the RED

Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of melting point, Guideline 151B-17(d), for all products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

This requirement is only applicable for technical grade active ingredients that are solid at room temperature. Methoprene is a liquid at room temperature; therefore, this requirement does not apply to any product contained in the Methoprene RED.

Best regards,

Kelly J. Parker

Regulatory Specialist

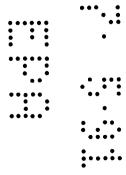
800/527-0512

CC: Phil Hutton, RD, EPA

Dick King, SRRD, EPA

Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific ID# 2724-RD-7 Zoecon RF-291 Emulsifiable Concentrate, EPA Rea. No. 2724-352 - Product Specific ID# 2724-RD-25 Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34 Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36 Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41 Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42 Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44 Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46 Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48 Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - **Product Specific ID# 2724-RD-50** Methoprene, EPA Reg. No. 2724-441 - **Product Specific ID# 2724-RD-56** (S)-Methoprene Technical, EPA Reg. No. 2724-442 - Product Specific ID# 2724-RD-51 Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439 Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22 Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23 Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24 Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26 Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27 ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28 Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29 Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30 Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31 ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33 Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49 Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson Product Management Team 18 U.S. Environmental Protection Agency Document Processing Desk (RED/RD-0030) Office of Pesticide Programs (H7504C) Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202

RE: Request for a Waiver of Stability

All Products Listed in the RED

Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of stability, Guideline 151B-17(j), for all products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

This requirement is only applicable for technical grade active ingredients. The stability of Methoprene can be found in MRID Number 00010927. All other products are end-products and manufacturing-products; therefore, this requirement does not apply to any product contained in the Methoprene RED.

Best regards,

Kelly J. Parker

Regulatory Specialist

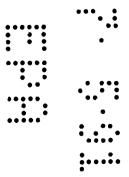
800/527-0512

CC: Phil Hutton, RD, EPA

Dick King, SRRD, EPA

Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25 Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34 Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36 Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41 Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42 Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44 Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46 Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48 Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50 Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439 Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22 Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23 Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24 Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26 Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27 ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28 Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29 Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30 Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31 ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33 Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49 Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

. 2.

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Cffice of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE:

Request for a Waiver of Solubility

All Products Listed in the RED

Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of solubility, Guideline 151B-17(g), for all products subject to the Methoprene Reregistration Eligibility Decision document—(see attached).

This requirement is only applicable for technical grade active ingredients. The solubility of Methoprene can be found in MRID Number 00010927. All other products are end-products and manufacturing-products; therefore, this requirement does not apply to any other product contained in the Methoprene RED.

Best regards,

Kelly J. Parker

Regulatory Specialist

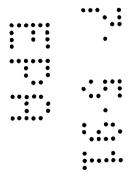
800/527-0512

CC: Phil Hutton, RD, EPA

Dick King, SRRD, EPA

Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific ID# 2724-RD-7 Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352⁻ - **Product Specific ID# 2724-RD-25** Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34 Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36 Altosid Llauid Larvicide, EPA Rea. No. 2724-392 - Product Specific ID# 2724-RD-41 Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42 Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44 Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46 Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48 Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50 Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439 Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22 Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23 Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - **Product Specific ID# 2724-RD-24** Zoecon RF-293 Methoprene Bolüs, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26 Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27 ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28 Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29 Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30 Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31 ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33 Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49 Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

20 May 1991

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mail 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE:

Request for an Extension of Storage Stability Data

Guideline 151B-17(I)

Product Specific ID# 2724-RD-25

EPA Reg. No. 2724-352

Dear Mr. Nelson:

Zoecon Corporation respectfully requests an extension for submission of storage stability data for the subject product. We would like to submit a final report for this study in November 1992.

According to FIFRA as amended in 1988, there is no legislated timeframe for submission of product specific data for List A products (although Lists B, C, and D are subject to the 8 month rule); therefore, the length of our requested extension should pose no regulatory problem. For storage stability studies, EPA currently requires 3 lots, 3 temperatures, and 1 year's worth of GLP data. In the best of circumstances, this is unachievable within 8 months.

According to 40 CFR § 160.29(c), "There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol." Considering all of the GLP storage stability studies required by the Methoprene RED, Zoecon would need to hire 50 more people to conduct the studies, as well as the inherent need to build more stability storage space. I've been told by management that these are not viable options. We have come up with a schedule that would allow Zoecon to comply with the RED by conducting the stability studies in shifts. This will also allow Zoecon to remain in compliance with § 160.29(c) and allow us to use available storage space.

Please let me know as soon as possible whether our request for an extension has been granted.

Best regards,

Kelly J. Parker

Regulatory Specialist

800/527-0512

CC: Phil Hutton, RD, EPA

Kelly of Parker

Karen Samek, SRRD, EPA

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

20 May 1991

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE:

Request for an Extension of Storage Stability Data

Guideline 151B-17(1)

Product Specific ID# 2724-RD-50

EPA Reg. No. 2724-427

Dear Mr. Nelson:

Zoecon Corporation respectfully requests an extension for submission of storage stability data for the subject product. We would like to submit a final report for this study in November 1992.

According to FIFRA as amended in 1988, there is no legislated timeframe for submission of product specific data for List A products (although Lists B, C, and D are subject to the 8 month rule); therefore, the length of our requested extension should pose no regulatory problem. For storage stability studies, EPA currently requires 3 lots, 3 temperatures, and 1 year's worth of GLP data. In the best of circumstances, this is unachievable within 8 months.

According to 40 CFR § 160.29(c), 'There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.' Considering all of the GLP storage stability studies required by the Methoprene RED, Zoecon would need to hire 50 more people to conduct the studies, as well as the inherent need to build more stability storage space. I've been told by management that these are not viable options. We have come up with a schedule that would allow Zoecon to comply with the RED by conducting the stability studies in shifts. This will also allow Zoecon to remain in compliance with § 160.29(c) and allow us to use available storage space.

Please let me know as soon as possible whether our request for an extension has been granted.

Best regards,

Kelly J. Parker

Regulatory Specialist

800/527-0512

CC:

Phil Hutton, RD, EPA Karen Samek, SRRD, EPA

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

S . 3.

Mr. Willie Nelson Product Management Team 18 U.S. Environmental Protection Agency Document Processing Desk (RED/RD-0030) Office of Pesticide Programs (H7504C) Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202

RE:

Request for a Waiver of Miscibility

All Products Listed in the RED

Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of miscibility, Guideline 151B-17(n), for all products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

This requirement is only applicable for emulsifiable liquids intended to be diluted with petroleum solvents. Although we do have emulsifiable liquids, they are not diluted with petroleum solvents; therefore, this requirement does not apply to any product contained in the Methoprene RED.

Best regards,

Kelly J. Parker

Regulatory Specialist

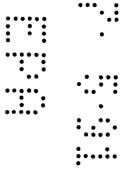
800/527-0512

CC: Phil Hutton, RD, EPA

Dick King, SRRD, EPA

Products

Zoecon RF-174 Flea Growth Regulator, EPA Rea. No. 2724-286 - Product Specific ID# 2724-RD-7 Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25 Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34 Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36 Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41 Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42 Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44 Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46 Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48 Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50 Methoprene, EPA Reg. No. 2724-441 - Product Specific ID# 2724-RD-56 (S)-Methoprene Technical, EPA Reg. No. 2724-442 - Product Specific ID# 2724-RD-51 Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439 Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22 Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23 Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24 Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26 Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27 ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28 Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29 Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30 Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31 ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33 Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49 Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Request for a Waiver of Oct/Water Partition Coefficient Data All End-Use Products Listed in the RED Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon respectfully requests a waiver of Octanol/Water Partition Coefficient Data, Guideline Number 151B-17(p) for all end-use products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

We understand that this requirement was part of the generic data requirement for the technical grade active ingredient. Data are being generated on the active ingredient and will be submitted by the April 1992 deadline. All other products are end-products and manufacturing-products; therefore, this requirement does not apply to any other product contained in the Methoprene RED.

Best regards,

Kelly J. Parker

Regulatory Specialist

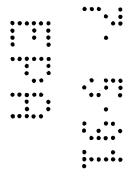
800/527-0512

CC: Phil Hutton, RD, EPA Dick King, SRRD, EPA

Products

Zoecon RF-174 flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific ID# 2724-RD-7 Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25 Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34 Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36 Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41 Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42 Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44 Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46 Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48 Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50 Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439 Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22 Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23 Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24 Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26 Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27 ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28 Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29 Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30 Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31 ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33 Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Request for a Waiver of Boiling Point

All Products Listed in the RED

Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests <u>a waiver of boiling point</u>, Guideline 151B-17(e), for all products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

This requirement is only applicable for technical grade active ingredients that are liquid at room temperature. The boiling point for Methoprene can be found in MRID Number 00010927. All other products are end-products and manufacturing-products; therefore, this requirement does not apply to any other product contained in the Methoprene RED.

Best regards,

Kelly J. Parker

Regulatory Specialist

800/527-0512

CC: Phil Hutton, RD, EPA

Dick King, SRRD, EPA

Products

ID# 2724-RD-7

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25

Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34

Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36

Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41

Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42

Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44

Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46

Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48

Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50

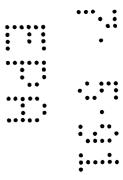
Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-50

ID# 2724-RD-439

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific

Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22
Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23
Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24
Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26
Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27
ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28
Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29

Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30 Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31 ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33 Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49 Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Request for a Waiver of Vapor Pressure

All Products Listed in the RED

Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of vapor pressure.

Guideline 151B-17(h), for all products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

This requirement is only applicable for active ingredients. The vapor pressure for Methoprene can be found in MRID Number 00010927. All other products are end-products and manufacturing-products; therefore, this requirement does not apply to any other product contained in the Methoprene RED.

Best regards,

Kelly J. Parker

Regulatory Specialist

800/527-0512

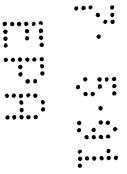
CC: Phil Hutton, RD, EPA

Dick King, SRRD, EPA

Jelly of Parker

Products

Zoecon RF-174 Flea Growth Regulator, EPA Rea. No. 2724-286 - Product Specific ID# 2724-RD-7 Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25 Kabat Tobacco Protector, EPA Rea. No. 2724-377 - Product Specific ID# 2724-RD-34 Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36 Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41 Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42 Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44 Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46 Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48 Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50 Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439 Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22 Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23 Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - **Product Specific ID# 2724-RD-24** Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26 Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27 ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28 Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29 Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30 Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31 ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33 Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49 Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52





United States Environmental Protection Agency Washington, D.C. 20460

Form Approved

OMB No. 2070-0107

Approval Expires 12-31-92

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address ZOECON CORPORATION-A SANDOZ CO. 12200 DENTON DRIVE DALLAS, TX. 75234				2. Case # and Name 0030 Methoprene Chemical # and Name 105401 Methoprene EPA Reg. No. 2724-427					3. Date and Type of DCI PRODUCT SPECIFIC ID# 2724-RD-50 MAR 2 1 1991	
4. Guideline Requirement Number	5. Study Title	PROTOCOL	l .	rogred eport 2 yrs	s S	6. Use Pattern	7. Test Substan		8. Time Frame	9. Registrant Response
151B-10 151B-11 141B-12 151B-13 151B-15 151B-16 151B-17(a) 151B-17(b) 151B-17(c) 151B-17(d) 151B-17(f) 151B-17(f) 151B-17(f) 151B-17(h) 151B-17(i) 151B-17(k) 151B-17(k)	Product Identity Manufacturing Process Discussion of Impurities Analysis of Samples Certification of limits Analytical method Color Physical state Odor Melting point Boiling point Density Solubility Vapor pressure pH Stability Flammability Storage stability					ALL	E E E E E E E E E E E E E E E E E E E	P P P P P P P P P	8 mos.	1 7 7 1 1 1 1 7 7 1 7 1 7
I acknowledige that under applicable is	le of Company's Authorized Representative_	nay bo					cory	11. Date 13. Phono 214/	1 July 1991 1 Number 1888-8726	

^{*}Correspondence Attached



United States Environmental Protection Agency Washington, D.C. 20460

Form Approved

OMB No. 2070-0107

Approval Expires 12-31-92

REQUIREMENTS STATUS AND REGISTRANTS RESPONSE

INSTRUCTIONS: Please type or print in ink. Please read carefully the attached instructions and supply the information requested on this form. Use additional sheet(s) if necessary.

1. Company name and Address ZOECON CORPORATION-A SANDOZ CO. 12200 DENTON DRIVE DALLAS, TX. 75234		2. Case # and Name 0030 Methoprene Chemical # and Name 105401 Methoprene EPA Reg. No. 2724-427					3. Date and Type of DCI PRODUCT SPECIFIC ID# 2724-RD-50 MAR 2 1 1991	
. Guideline 5. Study Title lumber	PROTOCOL		rogre epor	- 1	6. Use Pattern	7. Test Substance	8. Time Frame	9. Registrant Response
51B-17(m) 51B-17(n) 51B-17(o) 51B-17(p) 52B-10 52B-11 52B-12 52B-13 52B-13 52B-14 52B-15 52B-16 5-10(b)(1) S1B-17(n) Miscibility Corrosion characteristics Oct/Water partition coef. Acute oral toxicity Acute dermal toxicity Primary eye irritation Primary dermal irritation Dermal sensitization Hypersensitivity Incidents Prod. Perf. for mosquitoes (cesspools, septic tanks, and waste treatment settling ponds)					ALL	E	8 mos. 8 mos. 8 mos. 8 mos. 8 mos. 8 mos. 8 mos. 8 mos. 8 mos.	1 7 1* 7 4 4 1 4 1 7

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

20 May 1991

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE:

Request for an Extension of Storage Stability Data

Guideline 151B-17(1)

Product Specific ID# 2724-RD-50

EPA Reg. No. 2724-427

Dear Mr. Nelson:

Zoecon Corporation respectfully requests an extension for submission of storage stability data for the subject product. We would like to submit a final report for this study in November 1992.

According to FIFRA as amended in 1988, there is no legislated timeframe for submission of product specific data for List A products (although Lists B, C, and D are subject to the 8 month rule); therefore, the length of our requested extension should pose no regulatory problem. For storage stability studies, EPA currently requires 3 lots, 3 temperatures, and 1 year's worth of GLP data. In the best of circumstances, this is unachievable within 8 months.

According to 40 CFR § 160.29(c), 'There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.' Considering all of the GLP storage stability studies required by the Methoprene RED, Zoecon would need to hire 50 more people to conduct the studies, as well as the inherent need to build more stability storage space. I've been told by management that these are not viable options. We have come up with a schedule that would allow Zoecon to comply with the RED by conducting the stability studies in shifts. This will also allow Zoecon to remain in compliance with § 160.29(c) and allow us to use available storage space.

Please let me know as soon as possible whether our request for an extension has been granted.

Best regards,

Kelly J. Parker

Regulatory Specialist

800/527-0512

CC:

Phil Hutton, RD, EPA

Karen Samek, SRRD, EPA

Parker

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson Product Management Team 18 U.S. Environmental Protection Agency Document Processing Desk (RED/RD-0030) Office of Pesticide Programs (H7504C) Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202

RE:

Correspondence for Storage Stability and Corrosion Characteristics

All Products Listed in the RED

Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation conducts these studies together; therefore, the attached requests for extension of submitting storage stability data also apply to the corrosion characteristics portion of the study. We apologize for any inconvenience this oversight may have caused.

These requests are resubmitted here because we haven't received a response from EPA.

Best regards,

Kelly J. Parker

Regulatory Specialist

800/527-0512

CC: Phil Hutton, RD, EPA

Kelly of Parker

Dick King, SRRD, EPA

Products

Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25 Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34 Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36 Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42 Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48 Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50 Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439

Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23 ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28 Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29

Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30 Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31 ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33 Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49 Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52

A SANDOZ Company

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

1 July 1991

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE:

Request for a Waiver of Analysis of Samples

All End-Products and Manufacturing-Products Listed in the RED

Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a waiver of the analysis of samples, Guideline 151B-13, for all end-products and manufacturing-products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

These products are not technical active ingredients and they are not produced by an integrated system; therefore, this requirement is not applicable.

Best regards,

Kelly J. Parker

Regulatory Specialist

800/527-0512

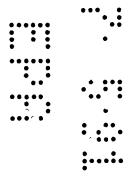
CC: Phil Hutton, RD, EPA

Dick King, SRRD, EPA

Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific ID# 2724-RD-7 Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25 Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34 Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36 Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41 Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42 Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44 Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific ID# 2724-RD-46 Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48 Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50 Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439 Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22 Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23 Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24 Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26 Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27 ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28 Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29 Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30 Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31 ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33 Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



A SANDOZ Company

1 July 1991

12200 Denton Drive, Dallas, Texas 75234, (214) 243-2321

Mr. Willie Nelson
Product Management Team 18
U.S. Environmental Protection Agency
Document Processing Desk (RED/RD-0030)
Office of Pesticide Programs (H7504C)
Room 266A, Crystal Mail 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE:

Request for a Waiver of Discussion of Formation of Impurities All End-Products and Manufacturing-Products Listed in the RED Case Number and Name: 0030 Methoprene

Dear Mr. Nelson:

Zoecon Corporation respectfully requests a walver of the discussion of impurities, Guideline 151B-12, for all end-products and manufacturing-products subject to the Methoprene Reregistration Eligibility Decision document (see attached).

These products are not technical active ingredients and they are not produced by an integrated system. The manufacturing and use history of these products show no reactions between the product and the packaging or between ingredients in the product. We've seen no reactions occurring between the product and the production equipment. These products do not contain impurities of toxicological concern such as N-nitrosamines, hexachiorobenzene, polychiorinated or polybrominated dibenzo-p-dioxins or furans.

According to EPA, "end-use products are typically mixtures having no reactions occurring." This is a true statement in the case of Methoprene-containing products. The chemists' time would be better spent generating product-specific product chemistry due by November, rather than theorizing about the possibilities of impurities. Therefore, we request this waiver.

Best regards,

Kelly J. Parker

Regulatory Specialist

800/527-0512

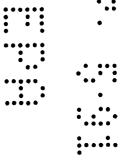
CC:

Phil Hutton, RD, EPA Dick King, SRRD, EPA

Products

Zoecon RF-174 Flea Growth Regulator, EPA Reg. No. 2724-286 - Product Specific ID# 2724-RD-7 Zoecon RF-291 Emulsifiable Concentrate, EPA Reg. No. 2724-352 - Product Specific ID# 2724-RD-25 Kabat Tobacco Protector, EPA Reg. No. 2724-377 - Product Specific ID# 2724-RD-34 Kabat Tobacco Protector Concentrate, EPA Reg. No. 2724-384 - Product Specific ID# 2724-RD-36 Altosid Liquid Larvicide, EPA Reg. No. 2724-392 - Product Specific ID# 2724-RD-41 Altosid Larvicide Concentrate, EPA Reg. No. 2724-393 - Product Specific ID# 2724-RD-42 Zoecon RF-299 RTU Carpet Pump Spray, EPA Reg. No. 2724-401 - Product Specific ID# 2724-RD-44 Zoecon RF-322 Ovicidal Pump Spray, EPA Reg. No. 2724-404 - Product Specific iD# 2724-RD-46 Zoecon RF-329 Ant Growth Regulator, EPA Reg. No. 2724-420 - Product Specific ID# 2724-RD-48 Zoecon RF-342 Emulsifiable Concentrate, EPA Reg. No. 2724-427 - Product Specific ID# 2724-RD-50 Zoecon RF-379 Mosquito Growth Regulator SR-20, EPA Reg. No. 2724-446 - Product Specific ID# 2724-RD-439 Zoecon RF-274 Fogger, EPA Reg. No. 2724-337 - Product Specific ID# 2724-RD-22 Zoecon RF-275 Pressurized Spray, EPA Reg. No. 2724-338 - Product Specific ID# 2724-RD-23 Zoecon RF-280 Aerosol, EPA Reg. No. 2724-339 - Product Specific ID# 2724-RD-24 Zoecon RF-293 Methoprene Bolus, EPA Reg. No. 2724-356 - Product Specific ID# 2724-RD-26 Zoecon RF-297 Aerosol, EPA Reg. No. 2724-360 - Product Specific ID# 2724-RD-27 ALTOSID CP-10, EPA Reg. No. 2724-367 - Product Specific ID# 2724-RD-28 Starbar Block IGR Cattle Supplement, EPA Reg. No. 2724-368 - Product Specific ID# 2724-RD-29 Granular IGR Cattle Supplement, EPA Reg. No. 2724-372 - Product Specific ID# 2724-RD-30 Block IGR Cattle Supplement, EPA Reg. No. 2724-373 - Product Specific ID# 2724-RD-31 ALTOSID Briquets, EPA Reg. No. 2724-375 - Product Specific ID# 2724-RD-33 Zoecon RF-292 Briquet, EPA Reg. No. 2724-421 - Product Specific ID# 2724-RD-49

Zoecon RF-330 ALTOSID Pellets, EPA Reg. No. 2724-448 - Product Specific ID# 2724-RD-52



PM # - 17

REG # - 2724-427

DATA ANALYST - Vim Hinkle

DATE PROCESSED - 1/16/91

THIS JACKET HAS BEEN FOUND TO BE DEFICIENT BY SIG FOR THE POLLOWING REASONS:

- 1. CURRENT ACCEPTED LABEL NOT STAMPED
- 2. CURRENT LABEL MISSING
- 3. CURRENT CSF MISSING
- 4. ACTIVE AND INERTS DO NOT = 100%
- 5. ADDITIONAL BRAND NAME (NO CODING REORD)
- 6. CURRENT INFORMATION ON FILE IS CORRECT (NO CHG REQRD)
- 7. CSF/LABEL/JACKET INFO. IS INCONSISTENT
- 8. SAME REG-NR ASSIGNED TO 2 PMS OR PRODUCTS
- 9. REG-NR IS OR NEEDS TO BE CANCELLED AND/OR TRANSFERRED
- 10. IN CSF, REG-NR IS CANCELLED NEED NEW REG. NR. FOR -
- 11. SITE/PEST INFO. MISSING FROM LABEL
- 12. RETURNED UNPROCESSED PER PM TEAM MEMBER REQUEST
- 13. NO SIGNAL WORD
- 14. NO ACTIVE/INERT PERCENTAGES ON LABEL
- 13. OTHER IN CSF, REG # FOR ACTIVE CHEMICAL CANNOT

 BE DETERMINED AS CURRENTLY ACCEPTED, TRANSFERRED OR

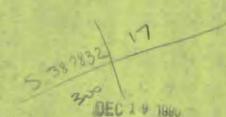
 CANCELLED. UNABLE TO DETERMINE CHEMICAL COMPOSITION OF

 S5947-109

PLEASE RESUBMIT THE ABOVE JACKET/S WHEN THE ABOVE DEFICIENCY/CIES HAVE BEEN CORRECTED TO:

SIG ROOM 263 557 - 1176

YOUR GOOPERATION IN RESOLVING THE DEPICIENCY/CIES IS GREATLY APPRECIATED.



Kelly Parker Zoecon Corporation A Sandoz Co. 12005 Ford Road, Suite 800 LB 44 Dallas, Texas 75234-7296

Subject: Zoecon RF-342 Emulsifiable Concentrate EPA Reg No. 2724-427 Your label submission dated December 13, 1989.

Dear Ms. Parker:

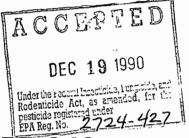
The labeling referred to above, submitted in connection with registration under the Pederal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Sincerely,

ffm Phil Hutton Product Manager (17) Insecticide/Rodenticide Branch Registration Division (H7505C)

Enclosure

SYMBOL	
SURNAME Basiler	
DATE 12-16/-90	975



TOTAL..... 100.0%

ZOECON RF-342 EMULSIFIABLE CONCENTRATE FOR TOBACCO

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Storage Facilities

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements.

NET CONTENTS:

INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects.

Almond moth (Ephestia cautella)
Cigarette beetle (Lasioderma serricorne)
Sawtooth grain beetle (Oryzaephilus surinamensis)
Red flour beetle (Tribolium castaneum)
Tobacco moth (Ephestia elutella)
Indian meal moth (Plodia Interpunctella)
Lesser grain borer (Rhyzopertha dominica)
Merchant grain beetle (Oryzaephilus mercator)
Confused flour beetle (Tribolium confusum)
Warehouse beetle (Trogoderma spp.)

PRECNUTIONARY STATEMENTS

HAZARDS TO HEMANS AND DOMESTIC ANIMALS - CAUTION: Harmful if inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1,000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

<u>Mixing Instructions</u>: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

STORAGE & DISPOSAL:

Storage - Store in a cool, dry place.

Pesticide Disposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

WARRANTY AND CONDITIONS OF SALE

Zoecon Corporation warrants that this product conforms to the chemical description on the label and is useful for the control of insect pests as described herein. Neither Zoecon nor the seller makes any other warranty, express or implied.

Zoecon Corporation
A Sandoz Company
Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724- 427 U.S. Patents 3,904,662 & 3,912,815 11898:0150E 276 EPA Est. 55947-CA-1 Made.in USA c 1988 Zoecon



DEC 19 1990

Undert. 3. secret insecticide, Fungacide, and findenticide flut, as amended, for the graphics regimered under

ZOECON RF-342 EMULSIFIABLE CONCENTRATE FOR TOBACCO

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Storage Facilities

ACTIVE INGREDIENTS:

This product contains 2.5 lb/gallon (300 grams/liter)
(S)-methoprene active ingredient.

KEEP OUT OF REACH OF CHILDREN.

CAUTION

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Indian meal moth (Plodia interpunctella)
Lesser grain borer (Rhyzopertha dominica)
Merchant grain beetle (Oryzaephilus mercator)
Confused flour beetle (Tribolium confusum)
Warehouse beetle (Trooderma spp.)

PRECAUTIONARY STATEMENTS

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ENVIRONMENTAL HAZARDS: Do not contaminate water when disposing of equipment washwaters.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1,000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-34Z to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

<u>Mixing Instructions</u>: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

STORAGE & DISPOSAL:

Storage - Store in a cool, dry place.

Perticide Disposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

WARRANTY AND CONDITIONS OF SALE

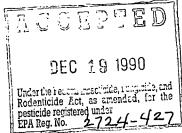
Zoecon Corporation warrants that this product conforms to the chemical description on the label and is useful for the control of insect pests as described herein. Neither Zoecon nor the seller makes any other warranty, express or implied.

Zoecon Corporation
A Sandoz Company
O Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724- 427 U.S. Patents 3,904,662 & 3,912,815 11898:0150E

1 -----

277 Era Est. 55947-CA-1 Made in USA c 1988 Zoecon



An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Storage Facilities

ACTIVE INGREDIENTS:

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements.

NET CONTENTS:

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Indian meal moth (Plodia interpunctella)
Lesser grain borer (Rhyzopertha cominica)
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DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply directly to tobacco being processed. Do not use this product in or on electrical equipment due to the possibility of shock hazard.

Application with Cold Aerosol Generators: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1,000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

STORAGE & DISPOSAL:

Storage - Store in a cool, dry place.

Pesticide Disposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility.

Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities.

[Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

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A Sandoz Company
Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724- 427 U.S. Patents 3,904,662 & 3,912,815 1189B:0150E 278 EPA Est. 55947-CA-1 Made in USA c 1988 Zoecon

5. Date Signed

4. Typed Nam

Kelly J. Parker

Paperwork Reduction Act Notice and Instructions *

Paperwork Reduction Act Notice

Public reporting burden for this collection of information is estimated to average of 0.85 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

Instructions

General

This form is to be used for all applications for new and amended registrations for pesticide products.

In order to process an application for new registration submitted on this form, the following material must accompany the application:

- Offer to Pay Statement (EPA Form 8570-22, -23, or -24). (If not exempted by 40 CFR 162.9-1(b).)
- 2. Confidential Statement of Formula (EPA Form 8570-4).
- 3. Five copies of draft labeling.
- 4. Three copies of any data submitted.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on $8\ 1/2\ x\ 11$ inch paper or as a mockup of the proposed label. If prepared as a mockup it should be constructed in such a way as to facilitate storage in an $8\ 1/2\ x\ 11$ inch file. Mockup labels significantly smaller than $8\ 1/2\ x\ 11$ inches should be mounted on $8\ 1/2\ x\ 11$ inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

Specific

Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A , for which you are submitting this application. For applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended registration actions, Section I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form.

Section I - This Section must be completed for both Registration and Amended Registration actions.

- Company/Product Number Insert your company number, if
 one has been assigned. This number may have been assigned
 to you as a basic registrant, a distributor, or as an establishment. If application is for an amendment, insert the registration number of the product.
- 2. Date Fill in the appropriate date.
- 3. Product Manager If known, fill in the name and number of the Product Manager.
- 4. Proposed Classification Specify the proposed classification for this product.
- 5. Name and Address of Applicant The name of the firm or person and address shown in your application is the person or firm to whom registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for thora in registration matters.

An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.

6. Product Name - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

Amendment Information

Section II - This Section must be completed for all applications submitted in connection with Amended Registration.

 Subject of Amendment - Check the appropriate block, and provide a brief explanation of the purpose(s) for the amendment, such as: "the addition of a site, pest, or crop"; "to change inert ingredient"; "general label revisions of precautionary statements," etc.

Packaging and Container Information

Section III - This Section must be completed for all applications submitted in connection with New Registration.

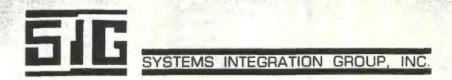
- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- Type of Retail Container Indicate type of container in which product will be marketed.
- Location of Net Contents Specify the net contents of all retail containers for your product.
- Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- Location of Use Directions Indicate the location of the use directions for your product.
- Manner in which label is affixed to product Indicate the method product labeling is attached to retail container.

Contact Point

Section IV - This Section must be completed for all Registration and Amended Registration applications.

- 1-5. Self-explanatory.
- 6. EPA Use Only.

EPA Form 8570-1 (Rev. 9-88)



DATE:	2	28	190	_	
TO:	PROD	UCT	MANAGER	7	
FROM:	SYST	EMS	INTEGRATION	GROUP,	INC.

THE FOLLOWING REGISTRATION JACKETS ARE RETURNED FOR CHEMICAL INGREDIENT IDENTIFICATION. PLEASE REFER TO THE "REQUEST FOR CHEMICAL NAME REVIEW" FORM ATTACHED TO EACH JACKET.

REG.	#	2724	- 42	27	
REG.	#				
REG.	#				
REG.	#				
REG.	#				
REG.	#_				
REG.	#				

the removale of	AP	PENDIX	A
-----------------	----	--------	---

1	Request vace	21.	28	70
1	Receipt date			
1	Return date:			
1	Requestor	N.	B.	
1	PMSD I	7		

REQUEST FOR CHEMICAL NAME REVIEW

Org. 5	IG (TS-7) Room 263 Phone 557-446
Name of Che	mical_
4, (
Synonym(s)	1. (Include trade names, co./research names, etc.) ,
	3.
Codes:	
	CAS
•	Caswell
	Other (specify)
escription:	
Product Na	une Zoecon RF-342 Emulsifiable Concentrate.
Product Ty	
Registrant	Zoecon Corporation.
	rile Symbol 2724-427
Active	ingredient Image Inert ingredient Image Other (specify)
haughnessy	code
	•



BEC 0 6 1989

Kelly Parker Zoecon Corporation A Sandoz Company 12005 Ford Road, Suite 800, LB 44 Dallas, TX 75234-7296

Subject: Zoecon RF-342 emulsifiable Concentrate

EPA Registration No. 2724-427

Changes in the DIRECTIONS FOR USE portion of the label as per our discussion on November 21, 1989.

Dear Kelly:

The labeling changes that we discussed on November 21, 1989 made in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, are acceptable. The following DIRECTIONS FOR USE label statements will be removed because they would not be achievable in tobacco processing plants:

"Cover or remove any tobacco or tobacco processing equipment during application. After spraying wash all equipment, benches, shelving, etc., where tobacco will be handled with an effective cleaning compound followed by a potable water rinse."

Submit five (5) copies of the final printed labeling.

Sincerely,

Phil Hutton

Product Manager 17

Insecticide/Rodenticide Branch Registration Division (H7505C)

	CONCURRENCES		
SYMBOL			
SURNAME Brales			
DATE 11-37-89			
EPA Form 1320-1 (12-70)		OFFICE	83LE COP

Phil,

Kelly called 11-21-89 & indicated

that some of the Direction for Use

Statements were impractical/imporsible

for tobacco proc. plants - Alog that you had

discussed it of Richard Fresh + the tobacco

folks back this summer - so il took the

otherment requirements out - Please advice.

US ENVIRONMENTAL PROTECT! OFFICE OF PESTICIDES PROGRAMS **REGISTRATION DIVISION (75-767)** WASHINGTON, DC 20460

DATE OF ISSUANCE

TERM OF ISSUANCE

NOTICE OF PESTICIDE: REGISTRATION

REREGISTRATION

(Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended)

NAME OF PESTICIDE PRODUCT

Zoucon #F-342 Emulsifiable Concentrate

NAME AND ADDRESS OF REGISTRANT (Include ZIP code)

Zoecon Corporation A Sandoz Company 12005 Ford Road, Suite 800, LB 44 Dallas, TX 75234-7296

NOTE: Changes in labeling formula differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above U.S. EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby Registered/Reregistered under the Federal Insecticide, Fungicide, and Rodenticide Act.

A copy of the labeling accepted in connection with this Registration/Reregistration is returned herewith.

Registration is in no way to be construed as an indorsement or approval of this product by this Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with PIFRA section 3(c)(7)(A) provided that you:

- 1. Submit/cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
- 2. Make the labeling changes listed below before you release the product for shipmenti
 - a. Add the phrase "EPA Registration No. 2724-427."
 - Add the following statements to the DIRECTIONS FOR USE portion of the label:

Do not apply directly to tobacco being processed. A Cover or remove any tobacco or tobacco processing equipment during application. After spraying, wash all equipment, benches, shelving, etc., where tobacco will be handled with an effective cleaning compound followed by a potable water rinse. '

	ATTA	CHMENT	IS APP	LICABLE
_		COLLINIC III	10 (1)	SIGURE

SIGNATURE OF APPROVING OFFICIAL

EPA Form 8570-6 (Rev. 5-76)

PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

c. The following statement must be added to the label after the HAZARDS TO HUMANS AND DOMESTIC ANIMALS portion of the label:

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

d. You must add the following statement to the use directions:

Do not use this product in or on electrical equipment due to the possibility of shock hazard.

This statement must be included until your submission of test data indicates that the product is safe to use near or on electrical equipment.

- 3. Include data on the corrosive characteristics of the product when you submit the rest of the storage stability data.
- 4. Submit five (5) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Phil Hutton

Product Manager (17)

Millfor

Insecticide-Rodenticide Branch Registration Division (H7505C)

Enclosures

OFFICE OF PESTICIDE PROGRAM (TS-767)
WASHINGTON, D.C. 20460

Please read instructions on reverse before com-

VLIA	APPLICATION	ON FOR PE	STICIDE: Y AMENDM	ENT A ploting.
			TION I	
1. COMPANY/PRODUCT NO. 2724-UET	August 4, 19		3. PRODUCT MANAGER	4. PROPOSED CLASSIFICATION
8. NAME AND ADDRESS OF AF			Phil Hutton/17	RESTRICTED
Zoecon Corporation				•
A Sandoz Company 12200 Denton Drive				
Dallas, Texas 7523				
Dailas, 10xas 7520	7 -			
CHECK IF THIS IS A	NEW ADDRESS			
Zoecon RF-342 Emuls	sifiable Concen	trate		
			TION II	
1. SUBJECT OF AMENDMENT				
_	RESPONSE TO AGEN			
_	ABEL IN RESPONSE TO	O AGENCY LE	TTER DATED	_
OTHER (explain be	low)			
Expedited re	view of an ame	ndment wh	ich only proposes to	enlit-off
a "secondary	" label & Labe	lling from	n a previously submi	tted
"primary" la			in a proviousity submit	
		SECT	ION III	
1. WILL THIS PRODUCT BE PA	CKAGED IN:			2. TYPE OF CONTAINER
CHILD-RESISTANT PAG	KAGING YES	ОиО		XMETAL
UNIT PACKAGING	YES NO			
If YES, unit pkg. wt	No. per conta	iner	-	PAPER
WATER - SOLUBLE PA	CHAGING TES T	No		OTHER (Specify)
If YES, pkg. wt.	No. per container .			_
3. LOCATION OF NET CONTEN	(TS 4, 5121	E(S) OF RETAI	LCONTAINER	
MLABEL CONT		oz 128		
S. LOCATION OF LABEL DIRE	CTIONS		IN WHICH LABEL IS AFFIXED	
MON LABEL		X LITHO		(y)
ON MATERIAL ACCOMPA	NYING PRODUCT	X STENC		•
		Cas	TION IV	• • • •
1. CONTACT POINT (Complete	items directly below for			S. DATE APPLICATION RECEIVED
if necessary, to process this applic	ation).			(Stamped)
NAME				****
Richard W. Fresh				
TITLE	100.1		TELEPHONE NO. (Included Area Code)	de
Manager, Regulator	y Affairs		214/888-8453	
2. SIGNATURE	1		TITLE anager, Regulatory A	ffaire
4. TYPED NAME		Ma	Is. DATE SIGNED	
Richard W. Fresh			8/4/89	

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Storage Facilities

ACTIVE INGREDIENTS:

This product contains 2.5 lb/gallon (300 grams/liter) (\underline{S}) -methoprene active ingredient.

KEEP OUT OF REACH OF CHILDREN COMMENTS in EPA Letter Dated:

CAUTION

NOV L7 1989

Under the rederal insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2724 - 427

See Back Panel for Additional Precautionary Statements.

NET CONTENTS:

INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (S)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects.

Almond moth (<u>Ephestia cautella</u>)
Cigarette beetle (<u>Lasioderma serricorne</u>)
Sawtooth grain beetle (<u>Oryzaephilus surinamensis</u>)
Red flour beetle (<u>Irtbolium castaneum</u>)
Tobacco moth (<u>Ephestia elutella</u>)
Indian meal moth (<u>Plodia interpunctella</u>)
Lesser grain borer (<u>Rhyzopertha dominica</u>)
Merchant grain beetle (<u>Oryzaephilus mercator</u>)
Confused flour beetle (<u>Tribolium confusum</u>)
Warehouse beetle (<u>Irogoderma</u> spp.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Harmful if inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Application with Cold Aerosol Generators: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1,000 square feet of surface area. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as reguired.

Mixing Instructions: Partially fill the mixing container with water, add Zoecon RF-342, and complete filling with recommended quantity of water. Use diluted spray solution will 24 hours of mixing. Agitate before each use.

STORAGE & DISPOSAL:

Storage - Store in a cool, dry place. Pesticide

pisposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting
from use of this product may be disposed of on site or at an approved waste disposal
facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then
offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary
landfill, or by other procedures approved by state and local authorities. [Plastic
Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or
puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and
local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple
rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and
local procedures.

WARRANTY AND CONDITIONS OF SALE

Zoecon Corporation warrants that this product conforms to the chemical description on the label and is useful for the control of insect pests as described herein. Neither Zoecon nor the seller makes any other warranty, express or implied.

Zoecon Corporation
A Sandoz Company
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-U.S. Patents 3,904,662 & 3,912,815 0789A:0150E EPA Est. 55947-CA-1 Made in USA c 28 Secon

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Storage Facilities

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient.

KEEP OUT OF REACH OF CHILDREN CEPTED With COMMENTS in EPA Letter Dated:

CAUTION

NOV 17 1989

Under the Federal Insecticide, and Rodenticide Act as Functicide, and Rodenticide Act as amended, for the Pesticide amended under EPA Reg. No. registered under \$724

See Back Panel for Additional Precautionary Statements.

427

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Lesser grain borer (Rhyzopertha dominica)
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DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Application with Cold Aerosol Generators: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of I ml per 1,000 square feet of surface area. Use spray equipment to achieve uniform treatment.

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<u>Mixing Instructions</u>: Partially fill the mixing container with water, add Zoecon RF-342, and complete filling with recommended quantity of water. Use diluted spray solution will hours of mixing. Agitate before each use.

STORAGE & DISPOSAL:

Storage - Store in a cool, dry place.

Pesticide

Disposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting
from use of this product may be disposed of on site or at an approved waste disposal
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landfill, or by other procedures approved by state and local authorities. [Plastic
Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or
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local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple
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Zoecon Corporation
A Sandoz Company
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-U.S. Patents 3,904,662 & 3,912,815 0789A:0150E

EPA Est. 55947-CA-1

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Storage Facilities

ACTIVE INGREDIENTS:	
(S)-Methoprene [Isopropyl(2 <u>E</u> ,4 <u>E</u> ,7 <u>S</u>)-	
11-methoxy-3,7,11-trimethy1-2,4-	
dodecadienoate]	32.8%
INERT INGREDIENTS:	
TOTAL	100 0%

This product contains 2.5 lb/gallon (300 grams/liter) (\underline{S}) -methoprene active ingredient.

KEEP OUT OF REACH OF CHILDREN EPTED With COMMENTS in EPA Letter Dated:

CAUTION

NOV 17 1989

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 2724-427

See Back Panel for Additional Precautionary Statements.



INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in cold aerosol generators and as a concentrate for an aqueous emulsive spray. (§)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects.

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Lesser grain borer (Rhyzopertha dominica)
Merchant grain beetle (Oryzaephilus mercator)
Confused flour beetle (Tribolium confusum)
Warehouse beetle (Trogoderma spp.)

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<u>Application as an Aqueous Spray</u>: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add Zoecon RF-342, and complete filling with recommended quantity of water. Use diluted spray solution will 24 hours of mixing. Agitate before each use.

STORAGE & DISPOSAL:

Storage - Store in a cool, dry place. Pesticide Disposal - Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. Container Disposal - [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

WARRANTY AND CONDITIONS OF SALE

Zoecon Corporation warrants that this product conforms to the chemical description on the label and is useful for the control of insect pests as described herein. Neither Zoecon nor the seller makes any other warranty, express or implied.

Zoecon Corporation
A Sandoz Company
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-U.S. Patents 3,904,662 & 3,912,815 0789A:0150E

EPA Est. 55947-CA-1 Mac SSA c 1989 Decon

A SANDOZ Company

12005 Ford Road, Suite 800, LB 44, Dallas, Texas 75234-7296 (214) 243-2321

August 4, 1989

Mr. Phil Hutton
Product Manager (17)
Insecticide-Rodenticide Branch
Office of Pesticide Programs
Document Processing Desk (AMEND)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

RE: Zoecon RF-342 Emulsifiable Concentrate EPA File Symbol 2724-UET A Secondary Label Split From the Master Label

Dear Mr. Hutton:

Thank you for meeting with us on August 1, 1989. Both you and Mr. Nelson were very helpful.

Based on the meeting, Zoecon Corporation is proposing to amend the label of Zoecon RF-342 Emulsifiable Concentrate (2724-UET). The amendment would provide for a secondary tobacco-use-only label split-off from the master label which contains both tobacco and food handling establishment directions. The proposed tobacco-use-only label deletes all references to food handling establishments or directions for use in food handling establishments.

I have included 5 copies of the proposed label.

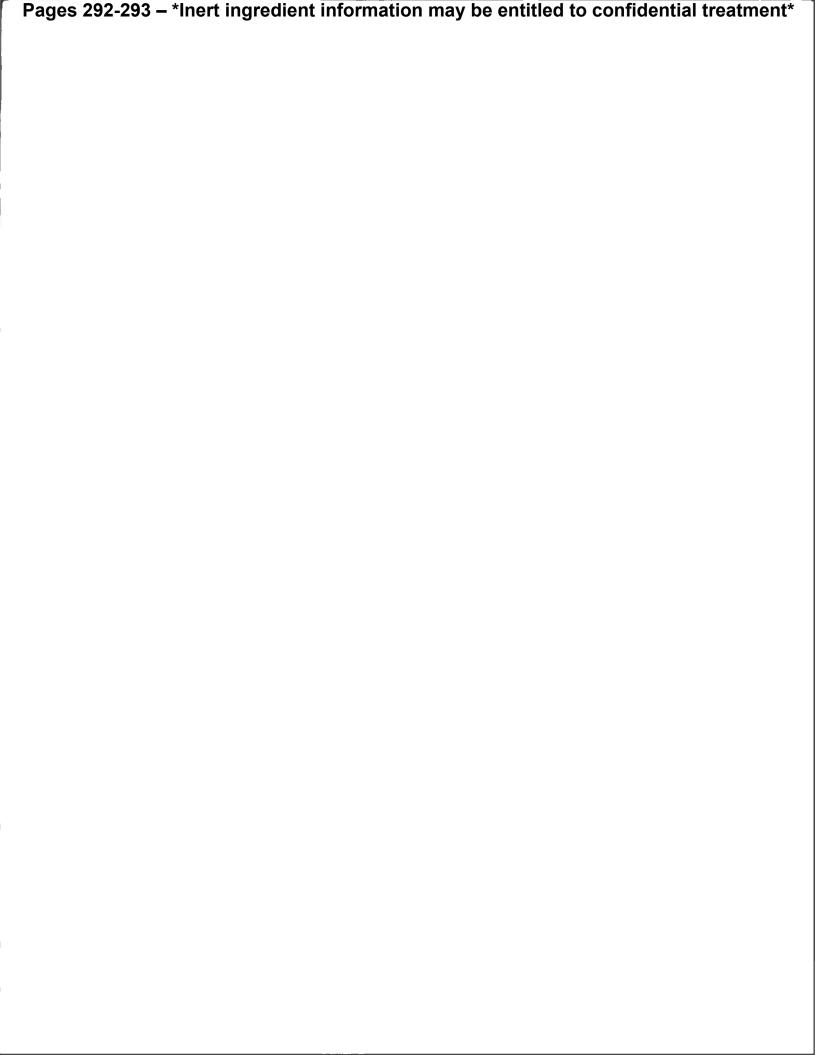
If you have questions on this amendment, please call me at 214/888-8453.

Best regards,

Richard W. Fresh

Manager, Regulatory Affairs

RWF:sw Enclosures



Sent by Fox

ZOECON CORPORATION 12005 FORD ROAD, SUITE 800 DALLAS, TEXAS 75234

UNATTENDED FAX #: MAIN PHONE #:

214/243-5613 214/243-2321

TELEX #:

730775 ZOEDAL

DATE:

October 27, 1989

TO:

Phil Hutton

#: 703/557-3106

LOCATION:

EPA

FROM:

Richard Fresh

NUMBER OF PAGES: 1 + COVER

Subject: Status of 2724-UET

ZOECON RF-342 Emulsifiable Concentrate

Phil:

On Aug. 1 of this year representatives of Philip Morris and Zoecon met with you to discuss a tobacco only label for the subject product. At that time I was told that the procedure would be to send in an amendment with the required modified label. The amendment would be administrative on your Team's part and would follow under the expedited review system (max. 90 day turn around).

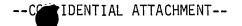
I sent the amendment into the Agency on Aug. 7, 1989. In my discussions with you on Oct. 11, 1989 you mentioned that there was some type of "mailroom snafu" according to your file book and that you would have to pull the jacket to see what the problem was. My questions to you are:

- 1. What is the problem?
- 2. What do we have to do, if anything to resolve it?
- 3. Since this supposedly was an expedited review, can Zoecon address the problem with you and get the product out of limbo and to the tobacco growers before the middle of November as we were told?

Thanks for your help.

Best regards,

3 3 3



Zoecon Corporation

A SANDOZ Company

12005 Ford Road, Suite 800, LB 44, Dallas, Texas 75234-7296 (214) 243-2321

August 15, 1989

Mr. Phil Hutton
Product Manager (17)
Insecticide-Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
Crystal Mall, Bldg. 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

RE: Zoecon RF-342 Emulsifiable Concentrate

Dear Phil:

Enclosed in the Confidential Attachment is a material safety data sheet for (Cross Reference 1). The supplier of the ingredient will provide the chemical identity directly to you in reference to our file. Since this product is a mixture of several inerts, it does not have a specific CAS number assigned to it.

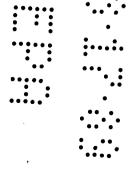
The supplier of (Cross Reference 2) has provided EPA with an authorization letter to reference their file at EPA (copy enclosed). The XF(ZS) formula does not contain xylene - the "XF" stands for xylene-free - and it is cleared for food use. The "(ZS)" stands for Zoecon Standard. Like (Cross Reference 1), this product is a mixture of several inerts and does not have a specific CAS number. I've requested a material safety data sheet. I'll forward a copy to you as soon as I receive it.

The dielectric breakdown voltage for the product is 39.2 KV. The final report for the test is being written and can be supplied to you as a condition of the registration.

Best regards,

Richard W. Fresh Manager, Regulatory Affairs

RWF:sw



CONFIDENTIAL ATTACHMENTS

CROSS REFERENCE NUMBER

THIS CROSS REFERENCE NUMBER NOTED IN THE LETTER DATED 15 AUGUST 1989 IS USED IN PLACE OF THE FOLLOWING WORDS. INFORMATION REGARDING THE DELETED WORDS ARE ATTACHED IMMEDIATELY BEHIND THIS PAGE.

DELETED WORD(S):

VOLUME PAGE(S)

REASON FOR DELETION

FIFRA REFERENCE

Identity of Inert Ingredient

10(d)(1)(C)

CROSS REFERENCE NUMBER 2

THIS CROSS REFERENCE NUMBER NOTED IN THE LETTER DATED 15 AUGUST 1989 IS USED IN PLACE OF THE FOLLOWING INFORMATION REGARDING THE WORDS. DELETED WORDS ARE ATTACHED IMMEDIATELY BEHIND THIS PAGE.

DELETED WORD(S):

VOLUME

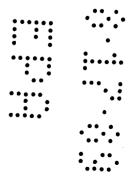
PAGE(S)

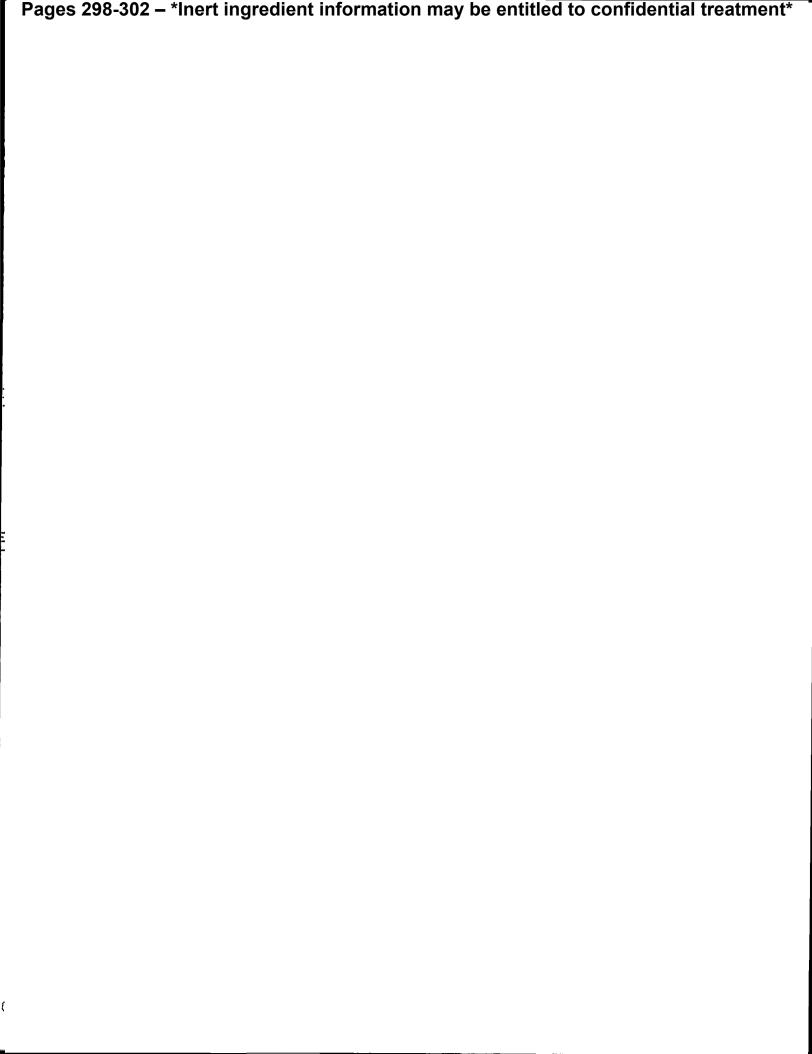
REASON FOR DELETION

FIFRA REFERENCE

Identity of Inert Ingredient

10(d)(1)(C)





Zoecon Corporation

A SANDOZ Company

12005 Ford Road, Suite 800, LB 44, Dallas, Texas 75234-7296 (214) 243-2321

August 15, 1989

Mr. Phil Hutton
Product Manager (17)
Insecticide-Rodenticide Branch
Registration Division (H7505C)
U.S. Environmental Protection Agency
Crystal Mall, Bldg. 2
1921 Jefferson Davis Hwy.
Arlington, VA 22202

RE: Zoecon RF-342 Emulsifiable Concentrate

Dear Phil:

Enclosed in the Confidential Attachment is a material safety data sheet for (Cross Reference 1). The supplier of the ingredient will provide the chemical identity directly to you in reference to our file. Since this product is a mixture of several inerts, it does not have a specific CAS number assigned to it.

The supplier of (Cross Reference 2) has provided EPA with an authorization letter to reference their file at EPA (copy enclosed). The XF(ZS) formula does not contain xylene - the "XF" stands for xylene-free - and it is cleared for food use. The "(ZS)" stands for Zoecon Standard. Like (Cross Reference 1), this product is a mixture of several inerts and does not have a specific CAS number. I've requested a material safety data sheet. I'll forward a copy to you as soon as I receive it.

The dielectric breakdown voltage for the product is 39.2 KV. The final report for the test is being written and can be supplied to you as a condition of the registration.

Best regards,

Richard W. Fresh

Manager, Regulatory Affairs

RWF:sw

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CONFIDENTIAL ATTACHMENTS

CROSS REFERENCE NUMBER 1

THIS CROSS REFERENCE NUMBER NOTED IN THE LETTER DATED 15 AUGUST 1989 IS USED IN PLACE OF THE FOLLOWING WORDS. INFORMATION REGARDING THE DELETED WORDS ARE ATTACHED IMMEDIATELY BEHIND THIS PAGE.

DELETED WORD(S):

DELETED WORD(3)

VOLUME PAGE(S)

REASON FOR DELETION

FIFRA REFERENCE

Identity of Inert Ingredient

10(d)(1)(C)

CROSS REFERENCE NUMBER 2

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DELETED WORD(S):

VOLUME

PAGE(S)

REASON FOR DELETION

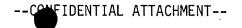
FIFRA REFERENCE

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Identity of Inert Ingredient

10(d)(1)(C)





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August 15, 1989

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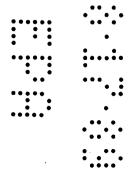
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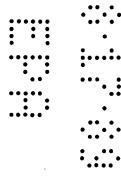
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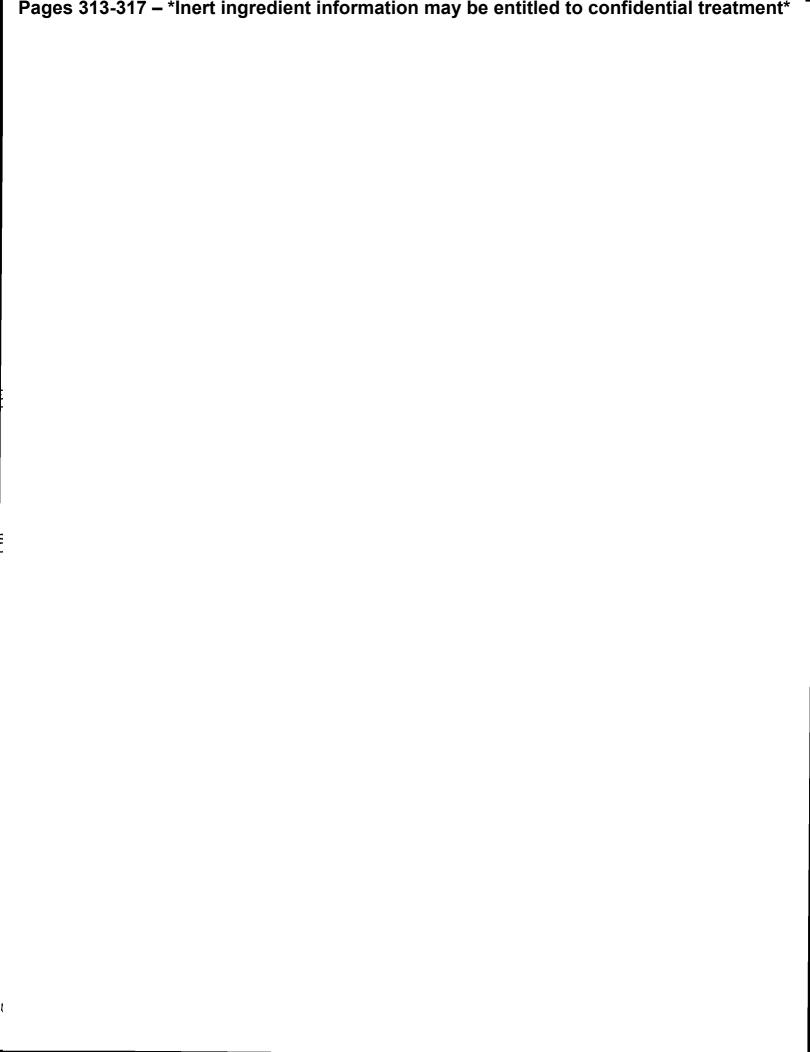
REASON FOR DELETION

FIFRA REFERENCE

-- Identity of Inert Ingredient

10(d)(1)(C)





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

10-1-89

Ms. Kelly Parker

Zeecon Corporation - A Sandoz Company
12005 Ford Road, Suite 800

LB 44

Dallas, TX 75234-7296

Dear Ms. Parker:

Subject: Zoecon RF-342 EC

EPA File Symbol 2724-UET

Your Letter Dated September 12, 1989 Withdrawing

Food Additive Petition No. 9H5588

The tolerance petition for food additive uses referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, has been withdrawn at your request. The file will be kept active for nonfood uses.

Sincerely yours,

Phil Hutton

Product Manager (17)

Insecticide-Rodenticide Branch Registration Division (H7505C)

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CONCUR	RENCES
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mydroprene but soocon is keeping petalin active for himrore

Zoecon Corporation

A SANDOZ Company

12005 Ford Road, Suite 800, LB 44, Dallas, Texas 75234-7296 (214) 243-2321

12 September 1989

Mr. Phil Hutton
Product Manager 17
U.S. Environmental Protection Agency
Insecticide-Rodenticide Branch
Registration Division (H7505C)
Document Processing Desk (CAN/WD)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Zoecon RF-342 Emulsifiable Concentrate EPA File Symbol 2724-UET Withdraw Food Additive Petition and Response to EPA Letter Dated 24 August 1989

Dear Mr. Hutton:

We would like to withdraw food additive petition number 9H5588. However, we would like to keep the file active for non-food uses. Please consider the label submitted by Richard Fresh on 4 August 1989 to be the current basic label. This product will be used as an insect growth regulator for the control of insect pests in tobacco processing and storage facilities.

Your letter of 24 August 1989 was a combination of two jackets -- RF-342 Emulsifiable Concentrate (containing methoprene) and RF-209 Cockroach Growth Regulator (containing hydroprene). Because we had received a draft copy of your letter in June, we responded in a letter dated 15 August 1989. The only outstanding question was regarding corrosion characteristics data. We will submit corrosion characteristics data as a condition of registration.

Best regards,

Kelly J. Parker

Regulatory Specialist

800/527-0512

S. ENVIRONMENTAL PROTECTION AGENCY OFFICE OF PESTICIDE PROGRAM (T5-767) WASHINGTON, D.C. 20460 PRGIS

Please read instructions

WEITH	APPLICATION FOR P	ESTICIDE: REGISTRA	ENT A pleting.
		CTION I	
1. COMPANY/PRODUCT NO.	Contembon 12: 1000	3. PRODUCT MANAGER	4. PROPOSED CLASSIFICATION GENERAL
2724-UET 5. NAME AND ADDRESS OF APP	September 12, 1989	Phil Hutton/17	RESTRICTED
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Zoecon Corporation			production of the second of th
A Sandoz Company			And the second second
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Zoecon RF-342 Emuls	ifiable Concentrate	and the second second	and the second second
		TION II	
1. SUBJECT OF AMENDMENT		8/24/89	
X RESUBMISSION IN	RESPONSE TO AGENCY LETTER D	DATED	
FINAL PRINTED LA	ABEL IN RESPONSE TO AGENCY L	ETTER DATED	The second of th
X OTHER (explain belo	οw)		
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Withdraw Foo	d Additive Petition		
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	Contract to the contract of		
	SEC	TION III	
1. WILL THIS PRODUCT BE PAC			2. TYPE OF CONTAINER
CHILD-RESISTANT PAC	KAGING YES NO		METAL .
UNIT PACKAGING	YES X NO		, DPLASTIC
If YES: unit pkg. wt.	No. per container		
WATER - SOLUBLE PAC	KAGING YES NO	ner en	OTHER (Specify)
If YES, pkg. wt.	No. per container		
1 100171011011011			1.1 T. 1
3. LOCATION OF NET CONTENT			
5. LOCATION OF LABEL DIREC	1,02.	R IN WHICH LABEL IS AFFIXE	TO PRODUCT
∑ ON LABEL	عند ا	OGRAPH OTHER (Special	
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ON MATERIAL ACCOMPAN			••••
CONTACT POINT (Complete is	SEC tems directly below for identification	CTION IV	6. DATE APPLICATION RECEIVED
if necessary, to process this applica		of individual to be contacted,	Talen (Ståmped) +
NAME	:	the second of the second	
Kelly J. Parker	or the state of t	and the second second	
TITLE		TELEPHONE NO. (Inclu	de
Regulatory Speciali		214/888-8726	
2, SIGNATURE	Danker	. тітье Regulatory Specialis	+
4. TYPEDNAME	wiker	B. DATE SIGNED	
Kelly J. Parker		9/12/89	

EPA Form 8570-1 (Rev. 5-81)

PREVIOUS EDITION IS OBSOLETE.

Ms. Kelly J. Parker Zoecon Corporation A Sandoz Company 12200 Denton Drive Dallas, TX 75234

Dear Ms. Parker:

Subject: Zoecon RF-342 Emulsifiable Concentrate EPA File Symbol 2724-UET Your Submission Dated June 9, 1988

The application for registration of the subject product has been reviewed against the data requirements for registration of pesticides, Part 158 of Title 40 of the Code of Federal Regulations, and the data compensation procedures established by Pesticide Registration (PR) Notice 85-3 of May 14, 1985.

The following deficiencies must be corrected before this application can be given further consideration.

Please provide the requested information for the following items:

- 1. Please provide two copies of the chemical identity of all components, Material Saftety Data Sheet, and CAS Numbers of:
- Please update the label storage and disposal statement per PR Notice 83-3 or 84-1. Use separate subheadings for storage, pesticide disposal, and container disposal.
- 3. Since your data matrix does not give the dielectrical breakdown voltage, you must add the following to the use directions (until you submit test data):

Do not use this product in or on electrical equipment due to the possibility of shock hazard.

52320: I: Nelson: C. Disk: KENCO: 07/28/89: CL: VO: EK: CT

			CONCURRENC	ÉS		
SYMBOL						
SURNAME				***************************************	 ***************************************	
DATE		••••••	 ************	***************************************	 	22
EPA Form 13	20-1 (12-70)					AL FILE COPY

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160/24223



- 4. Corrosion characteristics data must be submitted.
- 5. Your labeling makes reference to areas that are clearly designated as U.S. Department of Agriculture (USDA) meat and poultry processing plants. Before we can give your product further consideration for conditional registration you must either:
 - a. File a separate application with USDA to obtain approval in such processing plants, in which case the label wording should be changed to reflect USDA acceptance, or
 - b. Qualify your site designation to exclude USDA meat and poultry processing plants.

You must submit your application to:

Mr. Charles Edwards
Compound Evaluation Laboratory
Scientific Services, FSQS
Food Ingredient Assessment Division
U.S. Department of Agriculture
Building 306, BARC - East
Beltsville, MD 20705
Telephone: (301) 344-2566

Submit a copy of the approved application to EPA for your file.

Results of the Tolerance/Exemption Review

- 1a. All of the inert ingredients in RF-209 Cockroach Growth Regulator are cleared under 40 CFR 180.1001.
- 1b. If the intent of the proposed labeling is to limit application to food areas other than where food is served (i.e., food service establishments) then you should clarify the proposed labeling to specify that applications are not permitted in food service establishments.
- 2. Although no plant or animal metabolism studies for hydroprene were submitted in conjunction with the currently proposed use in food handling establishments, by analogy to methoprene, an IGR which is structurally related to hydroprene, the Agency can conclude, for the purpose of the currently proposed use, that the residue of concern is hydroprene per se.
- 3. Zoecon Method No. 307, although subjected to limited validation, appears to be adequate for the generation of hydroprene residue data on the food items tested. However, the method must undergo successful validation at the EPA laboratory in Beltsville, MD before a tolerance may be granted. You should send the hydroprene

-3analytical reference standard along with a Material Safety Data Sheet to: Mr. Terry Bundy U.S. EPA Environmental Research Center Pesticide and Industrial Chemicals Repository U.S. Environmental Protection Agency 2 Triangle Drive Research Triangle Park, NC 27709 In addition, to meet the requirements set forth in 40 CFR 158.240 and further addressed in 51 FR 187:34249-50 (September 26, 1986), you must develop data to determine the applicability of FDA aultiresidue methodology in monitoring hydroprene residues in foods. These protocols are available from NTIS under order number PB86203734/AS. Attached to this review are a decision tree for multiresidue method testing, some FDA suggestions for improving data from FDA multiresidue trials, and an FDA note regarding the availability of charcoal for use in FDA protocols. 4a. The submitted food item residue data for hydroprene cannot be used as a basis for establishing the proposed food additive tolerance of 1.5 parts per million, since the generated data do not reflect maximum residues likely to result from the proposed Section B label use pattern for Zoecon RF-209 Cockroach Growth Regulator in food handling establishments (see Comments/Conclusions in the enclosed review). 4b. You should be advised that EPA does not set food additive tolerances based on average residues obtained from an exaggerated (3X) application rate which are then normalized to an equivalent 1% rate. Food additive tolerances are established on the basis of the highest observed residue values in or on representative food commodities following treatment at the proposed 1X label rate. 4c. Although requested in the Dietary Exposure Branch August 2, 1985 memorandum, you did not provide storage stability data for food samples obtained in the submitted residue study. Food samples were stored up to 11 months at -20 °C prior to analysis. The date the residue study was conducted was also not provided. The Agency recommends that you submit a new residue study 4d. simulating treatment of food handling establishments with Zoecon RF-209 EC as a fogger treatment at the proposed label (1X) use rate. An additional separate fogger application may also be conducted at a 3X rate. The same food items, exposed in the same manner as in the current study should be included in the new residue study, however, the Agency recommends that food samples exposed for 30 minutes should be sampled 1 and 8 hours 324

-4following application. If needed, you should then repropose food additive tolerances to cover maximum expected residues on various food items exposed at the proposed use rate. Additionally, in conjunction with the new residue study, you will need to supply documented storage information as well as storage stability data which reflect the conditions (i.e., temperature, length of time, etc.) under which samples were stored. Please find enclosed a copy of the residue chemistry review for food additive tolerances. This application will be kept open for a period of 75 days to give you an opportunity to correct the deficiencies listed above. If you find that you need more time to satisfy the requirements, you should request an extension and commit yourself to satisfy the deficiencies within a reasonable stated period of time. If you do not comply with this procedure, the Agency may administratively withdraw your application from further consideration, and retire this file without further notice to you in accordance with the policy established by PR Notice 75-4 of August 27, 1975. Once this is done you will have to submit a complete new application should you wish to pursue the registration of your product after the application has been withdrawn. Sincerely yours, Phil Hutton Product Manager (17) Insecticide-Rodenticide Branch Registration Division (H7505C) Enclosures 325

Reg.	#		

CHEMISTRY CHECKLIST CONT'D

Data Matrix Requirement	9.	Data	Matrix	Requiremen
-------------------------------------------	----	------	--------	------------

[]	a)	Statement of Co	omposition - a	complete descrip	tion of	the ma	anufacturing/	′
		formulation pro	ocess. Describe	equipment used,	mixing	time,	temperature	etc

- Discussion of Formation of [Unintentional] Ingredients a brief description of impurities formed during the manufacturing/formulation process, in packaging, or during storage. If you do not expect any impurities during these stages, please so state.
- Certification of Limits upper and lower limits of each active and individually added inert component. The lower limit for the actives, must be the same as the label claim in pure active ingredient form.
- Analytical Method provide the methods used to analyze for the active ingredients.
- f) Physical State e.g. solid, liquid, pressurized liquid, etc.
 g) Odor in common terms.
- Density e.g. lbs/gallon for liquids or lbs/cu. ft. for solids.
- i) pH provide pH of product or pH of a specified water dilution.
- j) Oxidizing or Reducing note these characteristics if any.
- [] i) [] j) [] k) Flammability - flash point/flame extension.
 - Explodability note these characteristics if any.
 - Storage Stability the formulated product must be analyzed for its active ingredient at time zero and during a year of storage. The storage should be in warehouse conditions of temperature and humidity and stored in similar containers you will be using in the trade. Note: For the Storage Stability study you cannot reference the concentrate you are using to formulate your product.
 - Viscosity can be expressed in centipoise or centistokes.
 - Miscibility note these characteristics if product is an emulsifiable liquid and mixed with oil.
 - Corrosion Characteristics this information can be noted during the storage stability study. [] *) The State Breakdown Voltage - for products used near telects

og: JPK 9-22-88

Note: 1) Until your dielectric strength deta shows otherit is site to use near or on electrical equipment, warning on cabal 15 Needed.

2) We note the rest of storage stability data will be submitted, within 6-12 mos. of you Test starting date. Corrosion character-15 tics data should be submitted also.

PRODUCT CHEMISTRY CHECKLIST

Please provide the requested information for the following checked items:

- 1. [] Submit the product specific product chemistry and the data matrix for your product. Your product is not sufficiently similar to the product you referenced.
- 2. On the Confidential Statement of Formula (CSF) please provide the following:
 - [] a) Provide pH of product or pH at a specified water dilution.

[] b) density of product

] c) flash point of product

*[] d) flash point of product with the propellent.

in pure active form.

- e) flame extension of product including flashbacks if noted

 f) Provide the upper and lower Certified Limits based on the pure
 active ingredients rather than the technical or concentrate.

 Note that the lower limit of the active must be the same as the label claim
- [] g) Provide upper and lower Certified Limits of the individually added inerts.
- [] h)
- [] i)
- 3. [] Based on the current CSF dated ______ your product will not meet the label claim for the active ingredient. Please revise the label or the CSF so the information agrees.
- 4. Please provide the chemical identity of all components, MSDS and CAS #s of: (two 1)
 2)
 - The supplier may contact us directly referencing your file symbol/EPA

 Req. # in their response.

Green to China trivel. Secretly their Carvage and in the circles

- Please update the label Storage and Disposal Statement per PR 83-3 or PR-84-1.

 USE Seperate Sub-headings For Storage, Pesticide disposal

 Add a footnote to the label ingredient statement indicating: and contains petroleum distillates, xylene, xylene range aromatic solvent posal.
- 7. [] Add the heading PHYSICAL OR CHEMICAL HAZARDS to the label and the appropriate statement. See 40 CFR 162.10
- Since your data matrix does not give a dielectrical breakdown voltage, you must add the following to the use directions:

 Do not use this product in or on electrical equipment due to the possibility of shock hazard. (Until your submission of Test data)
- 9. [] Solvent used is not considered an active ingredient so either report it under inert ingredients on the label or provide the registration no. for the source product and justify its insecticidal properties.

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Food Handling Establishments

This product contains 2.5 lb/gallon (300 grams/liter)
(\$)-methoprene active ingredient.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements.

NET CONTENTS:

INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in mechanical foggers and as a concentrate for an aqueous emulsive spray. (5)-methoprene, unlike traditional posticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects.

Almond moth (Ephestia cautella)
Cigarette beetle (Lasioderma serricorne)
Savtooth grain beetle (Oryzaephilus surinamensis)
Red flour beetle (Iribolium castaneum)
Tobacco moth (Ephestia elutella)
Indian meal moth (Plodia interpunctella)
Lesser grain borer (Rhyzopertha dominica)
Herchant grain beetle (Oryzaephilus mercator)
Confused flour beetle (Iribolium confusum)
Marehouse beetle (Irigoderma spp.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Harmful If inheled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Method, Rate and Timing of Application: Do not apply directly to food or tobacco being processed. Cover or remove any food or tobacco and processing equipment during application. After spraying, wash all equipment, benches, shelving, etc., where food or tobacco will be handled with potable water.

Application with Mechanical Chemical Foggers: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water or food-grade oil as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1,000 'square feet. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

<u>Mixing Instructions</u>: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

Food Handling Establishments: Zoecon RF-342 is intended for use within industrial, institutional and commercial buildings. In food handling areas of such establishments, applications may be made by mechanical ULY fogging, spot treatment, or crack and crevice application. Food areas include areas for receiving, storage, packing (canning, bottling, wrapping, botting), preparing, edible waste storage, and enclosed processing systems (mills, edible oils, syrups). Do not apply Zoecon RF-342 directly to food being processed. Cover or remove all food during application. All food processing surfaces must be covered during treatment or thoroughly cleaned before using. After application thoroughly wash all equipment, banches, shelving, etc. where food may be handled.

Zoecon RF-342 is authorized by the USDA for use in federally inspected meet and poultry plants.

STORAGE & DSPOSAL *Store in a cool, dry place. Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sentary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

WARRANTY AND CONDITIONS OF SALE

Zoecon Corporation warrants that this product conforms to the chemical description on the label and is useful for the control of insect pests as described herein. Neither Zoecon nor the seller makes any other warranty, express or implied.

> Zoecon Corporation A Sandoz Company 12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-U.S. Patents 3,904,662 & 3,912,815 0588A:0118E:0007E EPA Est. 55947-CA-1 Made in USA c 1988 Zoecon

Form Approved OMB No. 2000-0012

9	E	PA	

S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAM (15-767)
WASHINGTON, D.C. 20469
CATION FOR DESTICIDE.

Please read instructions on reverse before com-

	APPLICATION	V FUR PE	STICIDE:	AMENDMEN	T A	, precing.
			ION I			
1. COMPANY/PRODUCT NO. 2724-UET	JUN 0 9 19	88	3. PRODUCT M. Phil Hutt		4. PROP	SED CLASSIFICATION GENERAL RESTRICTED
5. NAME AND ADDRESS OF APPL		ie)		- \ - / /	L	
Zoecon Corporation						į.
A Sandoz Company	•					·
12200 Denton Drive			•			
Dallas, Texas 75234	. .					
CHECK IF THIS IS A NEW	N ADDRESS	•				
6. PRODUCT NAME						
Zoecon RF-342 Emulsi	fiable Concent	*				
1. SUBJECT OF AMENDMENT		SECT	ION II			*
RESUBMISSION IN R	ESPONSE TO AGENCY	LETTER DA	TED			
FINAL PRINTED LAS						
_					•	
OTHER (explain below	"		·		•	
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* .						
						Market Commencer 1
		SECT	ION-III		 .	
1. WILL THIS PRODUCT BE PACK	AGED IN:				2. TYPE	OF CONTAINER
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UNIT PACKAGING Y					⊠ PL	ASTIC
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3. LOCATION OF HET CONTENTS	4. SIZE(S) OF RETAIL	CONTAINER		┧ .	
ABEL CONTAI	iner 1 oz	. to 128	oz. /		İ	
5. LOCATION OF LABEL DIRECT	IONS		//	EL IS AFFIXED T	O PRODU	CT
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if necessary, to process this application		,			(Stam)	bed)
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Kelly J. Parker						••••
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Zoecon Corporation

A SANDOZ Company
12005 Ford Road, Suite 800, Dallas, Texas 75234-7296, (214) 243-2321

June 9, 1988

Mr. Phil Hutton
Product Manager (17)
Insecticide - Rodenticide Branch
Registration Division (TS-767C)
U.S. Environmental Protection Agency
Crystal Mall, Building 2
1921 Jefferson Davis Highway
Arlington, VA 22202

RE: Zoecon RF-342 Emulsifiable Concentrate
Application for New Registration, Proj. #T87-7

Dear Mr. Hutton:

Enclosed, by reference or submission, are data to support registration of the subject product. This application includes the following volumes of data:

Volume I: Physical/Chemical Data - End-Use Product

Volume II: Study of Methoprene Residues in Representative Food Commodities Resulting from Exposure to Zoecon RF-209 Fogger

RF-342 Emulsifiable Concentrate is a biochemical pesticide product for use in tobacco processing and food handling establishments to control a variety of insect pests including the Cigarette beetle, Tobacco moth, Sawtooth grain beetle, Confused flour beetle, and the Warehouse beetle.

Zoecon RF-342 is essentially identical to FZ-515876, EPA Reg. No. 2724-405. The basic difference between the two products is in the isomeric composition of methoprene. Zoecon RF-342 contains (S)-methoprene; FZ-515876 contains racemic methoprene. The percentage of (S)-methoprene in RF-342 is one-half that of racemic in FZ-515876. Since (S)-methoprene is twice as active as racemic, the rate of activity of methoprene in the RF-342 is identical to the currently registered FZ-515876.

Zoecon RF-342 has also been formulated to contain only inerts cleared for food use and not on a list of Toxicological Concern. A description of each inert and its regulatory status is provided in the Product Chemistry... section (Volume I) of this application. Letters authorizing reference of the EPA files for these inerts are being forwarded by the inert suppliers.

Product Chemistry

A stability study is being conducted at room temperature and $50\ C$. An interim report of the data shows the product is stable at $50\ C$ (room temperature data are not available at this time). A full report will be provided as a condition of the registration.

The Confidential Statements of Formula are provided on EPA form 8570-4 and list the active and inert ingredients. We have deleted the lines on the form order to have adequate room to list all the ingredient information. Upper and lower certified limits were derived according to the standard certified limits described in 40 CFR 158.175, published in the Federal Register 53 (86) p. 15997.

Residue Data

According to the current regulations and guidelines, this application does not require residue data, a petition for tolerance or a petition for an exemption from tolerance.

The regulations provide, under 40 CFR 158.165(b)(i), that "residue chemistry data requirements shall apply to biochemical pesticide products when any one or more of the following conditions apply:

- (A) Tier II or III toxicology data are required.
- (B) The application of the product exceeds 0.7 ounces (20 grams) active ingredient per acre per application.
- (C) The application rate of the product exceeds a level determined to be comparable to 0.7 ounces active ingredient per application but the application rate is not expressable in terms of ounces per acre per application."

Tier II or III toxicity data were not required on (S)-methoprene. Furthermore, application of RF-342 does not exceed a level comparable to 0.7 ounces (20 grams) active ingredient per acre per application. Zoecon RF-342 is applied indoors in food handling establishments at a rate of 0.28864 grams per 1,000 square feet per application. This rate, when compared to an acreage application is almost half the 20 gram rate, att. .

12.57 grams per acre per application (see calculation below). Therefore, residue chemistry data would not be required for food handling elearance.

Calculation:

*S-methoprene in RF-342 is applied at a rate of 1 millilites per 1000 square feet.

*RF-342 contains 32.8% S-methoprene.

*The density of RF-342 is 0.88 grams per milliliter.

*One acre is equivalent to 43,560 square feet.

$$\frac{1 \text{ ml}}{1000 \text{ sq ft}} \times \frac{32.8 \text{ g}}{100 \text{ g}} \times .88 \text{ g} = \frac{0.28864 \text{ g S-methoprene}}{1000 \text{ sq ft}}$$

Thus,

$$0.28864$$
 X $43,560$ sq ft = 12.57 g / acre per application 1 acre

The current guidelines (153-3(a)(1)) state, "a petition for a tolerance or for an exemption from the requirement of a tolerance is required...when the following conditions are met:

- (i) The product is intended for use on food or feed crops or its use is expected to result in residues in or on food or feed; and
- (ii) The rate of application exceeds 0.7 ounces (20 grams) of the biochemical (active ingredient) per acre per application."

Again, these conditions aren't met because the rate of application of (S)-methoprene in the proposed product is less than 20 grams per acre per application. Application of RF-342 would also not result in residues in food or feed, as discussed below (153-3 (a)(3)).

Further, Part 153-3(a)(2) states that residue data requirements will be determined on a case-by-case basis for biochemicals applied directly to food or feed and for biochemicals with application rates not expressable in ounces per acre per application.

Zoecon RF-342 is not applied directly to food or feed and the application rate can be expressable in terms of ounces/grams per acre per application.

Finally, part 153-3(a)(3) of the guidelines states that, "residue data will not be required and an exemption from the requirement of a tolerance will be recommended for products intended for use on food or feed crops or for uses expected to result in residues in or on food, or feed, when the following conditions are met:

- (i) Toxicology data developed from Tier I testing ...indicate that testing at Tier II is not required; and
- (ii) The rate of application is equal to or less than 20 grams of biochemical (active ingredient) per acre per application." : •••

We do meet the conditions, 3(i) and 3(ii); however, use of • ** ** product would not result in residues in food or feed.

The proposed label states that the product is not to be applied directly to food being processed. The label directs the user to cover or remove any

food during application, to cover all food processing surfaces during treatment or to thoroughly cleanse before using, and to wash all equipment, benches, shelving, etc. where food may be handled after application.

We are not requesting a tolerance or an exemption from tolerance because the label directions ensure that the use of RF-342 will not result in substantive residues in food or feed and (S)-methoprene, a biochemical, is applied at less than 20 grams per acre per application.

Although residue chemistry data are not required, a simulated food handling establishment study is provided for your reference in Volume II. This study was conducted with FZ-515876 since it was originally planned for food-use development. Please note that the rate of racemic methoprene applied in the study is six times the application rate for (S)-methoprene in the proposed product. The residue data are presented with respect to (S)-methoprene in Appendix 6. This presentation supports the clearance of (S)-methoprene in food handling establishments. Appendix 7 provides a summary of the extensive toxicology data available on methoprene (both racemic and the (S)) for your reference.

<u>Toxicology</u>

Toxicology data described under Tier I of Part 158.165(c) are referenced. In addition, Appendix 7 of the residue study (Volume II) presents a summary of the toxicology data available on methoprene as noted above.

Because the toxicity of (S)-methoprene is equivalent to that of racemic methoprene and because (S)-methoprene is used at half the rate, the conversion from racemic methoprene to (S)-methoprene would not change the toxicity profile/category of the end-use product. The change in the formulation to incorporate only food-grade inert ingredients that are not on a list of toxicological concern would also not affect the end-use toxicity category. We are currently conducting toxicity studies on the proposed product in accordance with our company policy to have data on every product we sell. We will submit these studies to the Agency upon completion.

Labe 1

The proposed product label is the same as the label current; or FZ-515876 with the following exceptions:

- 1. We have included the Warehouse beetle as a target pest. Data shows that methoprene is effective against the Trogoderma species of beetles. The Warehouse beetle is the common Trogoderma species found in label use-areas. All other pests listed are currently on the FZ-515876 label.
- 2. The precautionary language has been updated to comply with current guideline requirements. The language is now more comprehensive.

- 3. We've simplified the dilution statement under "Application as an Aqueous Spray". The statement directs the user to dilute the product at 1 milliliter per 1 gallon rather than 10 milliliters per 10 gallons. This is consistent with the application directions, stated as 1 gallon per 1,000 square feet.
- 4. We've added the following directions for use in food handling establishments:

"Food Handling Establishments: Zoecon RF-342 is intended for use within industrial, institutional and commercial buildings. In food handling areas of such establishments, applications may be made by mechanical ULV fogging, spot treatment, or crack and crevice application. Food areas include areas for receiving, storage, packing (canning, bottling, wrapping, boxing), preparing, serving, edible waste storage, and enclosed processing systems (mills, edible oils, syrups). Do not apply Zoecon RF-342 directly to food being processed. Cover or remove all food during application. All food processing surfaces must be covered during treatment or thoroughly cleaned before using. After application thoroughly wash all equipment, benches, shelving, etc. where food may be handled."

5. The storage and disposal statement has been updated in accordance with PR Notice 83-3.

Efficacy

Under EPA's current policy of not requiring submission of efficacy data, none are being referenced or submitted at this time.

EPA's clearance of (S)-methoprene for use in food handling establishments is in the public interest. The toxicological profile of methoprene, a biochemical pesticide is well established. (S)-methoprene offers a safer alternative to use of conventional pesticides in food handling establishments.

Best Regards,

Kelly J. Parker

Regulatory Specialist

(800)527-0512

dianexfood/lgw

Study Title Page

Physical/Chemical Data - End-Use Product

Data Requirement

40 CFR 158.165(a)

Author

George J. Junginger

Completed On

January 15, 1988

Performing Laboratory

Zoecon Corporation
A Sandoz Company
12200 Denton Drive
Dallas, Texas 75234

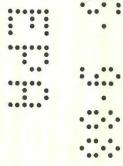
Laboratory Project ID

Project T87-7

Volume of Submission

Volume I

Page 1 of 12



STATEMENT OF CONFIDENTIALITY CLAIM

Information claimed confidential on the basis of its falling within the scope of FIFRA section 10(d)(1)(A), (B), or (C) has been removed to a confidential appendix, and is cited by cross-reference number in the body of the study. Further, this document is proprietary and the information contained herein should not be reviewed, abstracted, or used by any person without the express consent of Zoecon Corporation, A Sandoz Company, except that the information may be used by personnel of the EPA as necessary to carry out the requirements of the Agency (EPA).

Company: Zoecon Corporation, A Sandoz Company

Company Agent: Kelly J. Parker

Date: 9 June 1988

Title: Regulatory Specialist

Signature: Kelly of Parker

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Food Handling Establishments

ACTIVE INGREDIENTS:	
(S)-Methoprene [Isopropy1(2E,4E,7S)-11-methoxy-	
3,7,11-trimethy1-2,4-dodecadienoate]	32.8%
INERT INGREDIENTS:	67.2%
TOTAL	100.0%

This product contains 2.5 lb/gallon (300 grams/liter)
(\$)-methoprene active ingredient.

KEEP OUT OF REACH OF CHILDREN

CAUTION

See Back Panel for Additional Precautionary Statements.



INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in mechanical foggers and as a concentrate for an aqueous emulsive spray. (5)-methoprene, unlike traditional posticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects.

Almond moth (Ephestia cautella)
Cigaretta beetle (Lasioderma serricorne)
Sawtooth grain beetle (Dryzaephilus surinamensis)
Red flour beetle (Iribolium castanaum)
Tobacco moth (Ephestia elutella)
Indian meal moth (Piodia interpunctella)
Lesser grain boerle (Rhyzopertha dominica)
Herchant grain beetle (Oryzaephilus mercator)
Confused flour beetle (Iribolium confusum)
Marehouse beetle (Irigoderma spp.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Harmful if inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Method. Rate and Timing of Application: Do not apply directly to food or tobacco being processed. Cover or remove any food or tobacco and processing equipment during application. After spraying, wash all equipment, benches, shelving, etc., where food or tobacco will be handled with lotable water.

Application with Mechanical Chemical Foggers: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water er food-grade oil as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1,000 square feet. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallom of water. Apply at a rate of 1 gallom of diluted solution per 1,000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pasts. Repeat application as required.

<u>Mixing Instructions</u>: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each use.

Food Handling Establishments: Zoecon RF-342 is intended for use within industrial, institutional and commercial buildings. In food handling areas of such establishments, applications may be made by mechanical ULV fogging, spot treatment, or crack and crevice application. Food areas include areas for receiving, storage, packing (canning, bottling, wrapping, boxing), preparing, edible wasts storage, and enclosed processing systems (mills, edible oils, syrups). Do not apply Zoecon RF-342 directly to food being processed. Cover or remove all food during application. All food processing surfaces must be covered during treatment or thoroughly cleaned before using. After application thoroughly wash all equipment, benches, shelving, stc. where food may be handled.

Zoacon RF-342 is authorized by the USDA for use in federally inspected meet and poultry plants.

STORAGE & DISPOSAL. Store in a cool, dry place. Do not contaminate water, food, or feed by storage or disposal. Mastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of saoks. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

WARRANTY AND CONDITIONS OF SALE

Zoecon Corporation warrants that this product conforms to the chemical description on the label and is useful for the control of insect pests as described hereia. Neither Zoecon nor the seller makes any other warranty, express or implied.

Zoecon Corporation
A Sandoz Company
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-U.S. Patents 3,904,662 & 3,912,815 0588A:0118E:0007E EPA Est. 55947-CA-1 Made in USA c 1988 Zoecon

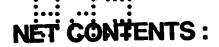
An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Food Handling Establishments

ACTIVE INGREDIENTS: (\underline{S})-Methoprene [Isopropyl($2\underline{E}, 4\underline{E}, 7\underline{S}$)-11-methoxy-INERT INGREDIENTS: 67.2% TOTAL..... 100.0%

This product contains 2.5 lb/gallon (300 grams/liter) (S)-methoprene active ingredient.

KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel for Additional Precautionary Statements.



INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in mechanical foggers and as a concentrata for an aqueous emulsive spray. (5)-methoprene, ualike traditional pesticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects.

Almond moth (Ephestia cautella)
Cigarette beetle (Lasioderma serricorne) Sawtooth grain beetle (Oryzaephilus surinamensis) Red flour beetle (Tribolium castaneum) Ned flour bestie (Irribolium Lasteneum)
Tobacco moth (Ephestia eluteila)
Indian meal moth (Plodia interpunctella)
Lesser grain borer (Rhyzopertha dominica)
Merchant grain beetle (Orgzapethius mercator)
Confused flour beetle (Tribolium confusum) Marehouse beetle (Trogoderma spp.)

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS - CAUTION: Harmful it inhaled or absorbed through skin. Avoid breathing vapors or spray mist. Avoid contact with skin, eyes or clothing. In case of contact, immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.

PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Method, Rate and Timing of Application: Do not apply directly to food or tobacco being processed. Cover or remove any food or tobacco and processing equipment during application. After spraying, wash all equipment, benches, shelving, etc., where food or tobacco will be handled with potable water.

Application with Mechanical Chemical Foggers: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water or food-grade oil as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1,000 square feet. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow apray mist to settle. Do not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallom of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat application as required.

Mixing Instructions: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each

Food Handling Establishments: Zoecon RF-342 is intended for use within industrial, institutional and commercial buildings. In food handling areas of such establishments, applications may be made by mechanical ULY fogging, spot treatment, or crack and crevice application. Food areas include areas for receiving, storage, packing (canning, bottling, wrapping, bosing), preparing, edible waste storage, and enclosed processing systems (mills, edible oils, syrups). Do not apply Zoecon RF-342 directly to food being processed. Cover or remove all food during application. All food processing surfaces must be covered during treatment or thoroughly cleaned before using. After application thoroughly wash all equipment, benches, shelving, etc. where food may be handled.

Toucon RF-342 is authorized by the USDA for use in federally inspected meat and poultry plants.

STORAGE & DISPOSAL "Store in a cool, dry place. Do not contaminate water, food, or feed by storage or disposal. Wastes resulting from use of this product may be disposed of on site or at an approved waste disposal facility. [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning. or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local or puncture and dispose of in an approved sentency landing, or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of seoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved State and local procedures.

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> Zoecon Corporation A Sandoz Company 12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-U.S. Patents 3,904,662 & 3,912,815 0588A:0118E:0007E EPA Est. 55947-CA-1 Made in USA c 1988 Zoecon

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Food Handling Establishments

This product contains 2.5 lb/gallon (300 grams/liter)
(\$)-methoprene active ingredient.

KEEP OUT OF REACH OF CHILDREN CAUTION

See Back Panel for Additional Precautionary Statements.

NET CONTENTS:

INTRODUCTION: Zoecon RF-342 is an emulsifiable formulation of the insect growth regulator methoprene. It is designed for use in mechanical foggers and as a concentrate for an aqueous emulsive spray. (5)-methoprene, unlike traditional pesticides, does not immediately kill insects; instead it interferes with the normal processes of insect development and prevents adult emergence. Zoecon RF-342, when used according to label directions, controls the following insects:

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Confused flour beetle (Tribolium confusum)
Marehouse beetle (Trogoderma spr.)

PRECAUTIONARY STATEMENTS

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PHYSICAL OR CHEMICAL HAZARDS: Do not use or store near heat or open flame.

DIRECTIONS FOR USE: It is a violation of Faderal law to use this product in a manner inconsistent with its labeling.

Method, Rate and Timing of Application: Do not apply directly to food or tobacco being processed. Cover or remove any food or tobacco and processing equipment during application. After spraying, wash all equipment, benches, shelving, etc., where food or tobacco will be handled with potable water.

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EPA Est. 55947-CA-1 Mede in USA c 1988 Zoecon

An Insect Growth Regulator for the Control of Insect Pests in Tobacco Processing and Food Handling Establishments

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KEEP OUT OF REACH OF CHILDREN

CAUTION

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Warehouse beetle (Tripoderma spp.)

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DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a menner inconsistent with its

Method, Rate and Timing of Application: Do not apply directly to food or tobacco being processed. Cover or remove any food or tobacco and processing equipment during application. After spraying, wash all equipment, benches, shelving, etc., where food or tobacco will be handled with potable water.

Application with Mechanical Chemical Foggers: Apply Zoecon RF-342 as a mist or aerosol. Dilute with water or food-grade oil as required following the instructions of the spray equipment manufacturer. Apply Zoecon RF-342 at the rate of 1 ml per 1,000 square feet. Use spray equipment to achieve uniform treatment.

Close room or warehouse and shut off all ventilating systems. Apply the product as a fine mist in the air above the trays, shelves, and in areas where dust may accumulate. Leave the room closed for 30 minutes to allow spray mist to settle. Bo not remain in treated area and ventilate before entry. Repeat application as required.

Application as an Aqueous Spray: Prepare a diluted spray solution by adding 1 ml of Zoecon RF-342 to 1 gallon of water. Apply at a rate of 1 gallon of diluted solution per 1,000 square feet of surface area with any low pressure sprayer typically used for indoor applications. Treat all areas which may harbor insect pests. Repeat applications as required.

<u>Mixing Instructions</u>: Partially fill the mixing container with water, add Zoecon RF-342, mix and complete filling with recommended quantity of water. Use diluted spray solution within 24 hours of mixing. Agitate before each

Food Handling Establishments: Zoecon RF-342 is intended for use within industrial, institutional and commercial buildings. In food handling areas of such establishments, applications may be made by mechanical ULV fooging, spot treatment, or crack and crevice application. Food areas include areas for receiving, storage, packing (canning, bottling, wrapping, botting), preparing, edible waste storage, and anclosed processing systems (mills, edible oils, syrups). Do not apply Zoecon RF-342 directly to food being processed. Cover or remove all food during application. All food processing surfaces must be covered during treatment or thoroughly cleaned before using. After application thoroughly wash all equipment, benches, shelving, etc. where food may be handled.

Zoncon RF-342 is authorized by the USDA for use in federally inspected meat and poultry plants.

STORAGE & DISPOSAL *Store in a cool, dry place. Do not contaminate water, food, or feed by storage or disposal. Water resulting from use of this product may be disposed of on site or at an approved methodisposal facility. [Metal Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in an approved sanitary landfill, or by other procedures approved by state and local authorities. [Plastic Containers]: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a senitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. [Glass Containers]: Triple rinse (or equivalent). Then dispose of in a senitary landfill or by other approved State and local procedures.

WARRANTY AND CONDITIONS OF SALE
Zoecon Corporation warrants that this product conforms to the chemical description on the label and is useful for
the control of insect pests as described herein. Neither Zoecon nor the seller makes any other warranty, express
or implied.

Zoecon Corporation
A Sandoz Company
12200 Denton Drive, Dallas, Texas 75234

EPA Reg. No. 2724-U.S. Patents 3,904,662 & 3,912,815 0588A:0118E:0007E EPA Est. 55947-CA-1 Made in USA c 1988 Zoecon Zoecon RF-342 Emulsifiable Concentrate

DATE:

JUN 0 9 1988

Application for New Registration

Active Ingredient: $32.8\% (\underline{S})$ -Methoprene

Part 158.165(a) Biochemical Product Analysis Data Requirements

Regulations Part 158/ Guideline No.	Name of Test	<u>Data</u>
151-10	Product Identity & Disclosure of Ingredients	On Confidential Statement of Formula
151-11	Manufacturing Process	Description of materials and manufacturing process are provided in Volume I of this application.
151-12	Discussion of Formation of Unintentional Ingredients	There are no known reactions between the active ingredient and the other ingredients or the packaging. Therefore, the only source of impurities would be associated with the registered active ingredient and the inerts. Identifying information on the inerts is on file at the Agency or provided in connection with this application.
151-13	Analysis of Samples	Not applicable. Product is not produced by an integrated formulation system (Footnote (iii) 40 CFR 158.165(a)
151-15	Certification of Limits	On the Confidential Statement of Formula.

Regulations Part 158/		
<u>Guideline No.</u>	Name of Test	<u>Data</u>
151-16	Analytical Method	Method is provided in Volume I of this application.
151-17	Physical & Chemical Characteristics	Data applicable to this end-use product is provided in Volume I of this application.
	Color	Light amber, transparent
	Physical State	Liquid @ 20°C
	Odor	Faint, fruity
	Specific Gravity	0.88 @ 25°C
	рН	6.4 @ 20°C
	Flammability	131°F Flash
	Storage Stability	Provided following this page
	Viscosity	26 cps @ 20°C
	Miscibility	Completely miscible in water and food-grade oil.
	Corrosion Characteristics	No corrosion noted in storage.
	Dielectric Breakdown Voltage	Study in progress. Will be O submitted upon completion.
151-18	Submittal of Samples	Not applicable. Product is not produced by an integrated formulation system (Footnote (iv) 40 CFR 158.165(a).
		••••
2RF342.DOC		••••

DATA REQUIREMENTS LISTING

Zoecon RF-342 Emulsifiable Concentrate

JUN 0 9 1988

Application for New Registration

Active Ingredient: $32.8\% (\underline{S})$ -Methoprene

Part 158.165(b) Biochemical Pesticides Residue Data Requirements

Regulations Part 158/ Guideline No.	Name of Test	Data
153-3	Chemical Identity	Refer to Confidential Statement of Formula provided with this application.
153-3	Directions for Use	Refer to label provided.
153-3	Magnitude of Residue	
	Meat/Milk/Poultry/Eggs	Not applicable; pesticide will not occur as a residue in livestock feed and will not be applied directly to livestock.
	Food Handling	Tolerance or exemption from tolerance is not required; however, a relevant study is provided in Volume II of this application.

2RF342.DOC

DATA REQUIREMENTS LISTING

Zoecon RF-342 Emulsifiable Concentrate

DATE:

JUN 0 9 1988

Application for New Registration

Active Ingredient: $32.8\% (\underline{S})$ -Methoprene

Part 158.165(c) Biochemical Pesticides Toxicology Data Requirements

Regulations Part 158/	Name of Table	Della
<u>Guideline No.</u>	Name of Test	Data
	Acute Testing	
152-10	Acute Oral Toxicity	Reference data on file for FZ-515876, Apex 5E, Methoprene Technical and (S)-Methoprene Technical, EPA Reg. No. 2724-405, 55947-88, 55947-90, 55947-109 respectively.
152-11	Acute Dermal Toxicity	Reference data on file for FZ-515876, Apex 5E, Methoprene Technical and (S)-Methoprene Technical, EPA Reg. No. 2724-405, 55947-88, 55947-90, 55947-109 respectively.
152-12	Acute Inhalation Toxicity	Reference data on file for FZ-515876, Apex 5E, Methoprene Technical and (S)-Methoprene Technical, EPA Reg. No. 2724-405, 55947-88, 55947-90, 55947-109 respectively.
152-13	Primary Eye Irritation	Reference data on file for FZ-515876, Apex 5E, Methoprene Technical and (S)-Methoprene Technical, EPA Reg. No. 2724-405, 55947-88, 55947-90, 55947-109 respectively.

Regulations Part 158/	Name of Tost	Data
Guideline No. 152-14	Name of Test Primary Dermal Irritation	Data Reference data on file for FZ-515876, Apex 5E, Methoprene Technical and (S)-Methoprene Technical, EPA Reg. No. 2724-405, 55947-88, 55947-90, 55947-109 respectively.
152-15	Hypersensitivity Study	Not applicable. Repeated skin contact does not result under normal conditions of use. Footnote (iii) 40CFR Part 158.165(c).
152-20	90-Day Feeding	Accession Number 093595, Page C-111.
	90-Day Dermal	Not applicable; use will not involve purposeful application to human skin or prolonged skin exposure.
	90-Day Inhalation	Not applicable; use will not result in repeated inhalation exposure at a concentration likely to be toxic.
	Teratogenicity	Not applicable; product use does not require a tolerance, or food additive regulation and would not result in significant exposure to female humans. Footnote (ix), 40 CFR 158.165. However this data can be referenced by Accession No. 242045, Page C-20 and C-49
2RF342.DOC		

DATA REQUIREMENTS LISTING

Zoecon RF-342 Emulsifiable Concentrate

DATE:

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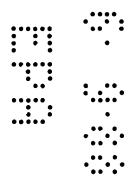
Application for New Registration

Active Ingredient: $32.8\% (\underline{S})$ -Methoprene

Part 158.165(d) Nontarget Organism, Fate and Expression Data Requirements

Not applicable; Product is an indoor use biochemical pesticide with a low volume application. Its use would not result in terrestrial or aquatic exposure.

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DATA REQUIREMENTS LISTING

JUN 0 9 1988

Zoecon RF-342 Emulsifiable Concentrate

DATE:

Application for New Registration

Active Ingredient: $32.8\% (\underline{S})$ -Methoprene

Part 158.165(d) Nontarget Organism, Fate and Expression Data Requirements

Not applicable; Product is an indoor use biochemical pesticide with a low volume application. Its use would not result in terrestrial or aquatic exposure.

2RF342.DOC



A SANDOZ Company 12005 Ford Road, Suite 800, Dallas, Texas 75234-7296, (214) 243-2321

TRANSMITAL DOCUMENT

PRODUCT NAME:

Zoecon RF-342 Emulsifiable Concentrate

TYPE OF SUBMISSION:

Application for New Registration

COMPANY:

Zoecon Corporation A Sandoz Company 12200 Denton Drive Dallas, Texas 75234

OFFICIAL:

Kelly J. Parker

Regulatory Specialist

SIGNATURE:

DATE:

June 9, 1988

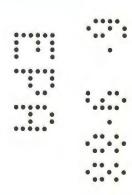
MRID NUMBER:

DESCRIPTION:

K. Parker, 6/9/88: Physical/Chemical Data-End-Use Product, Zoecon Corporation, A Sandoz

Company, Project T87-7, Unpublished.

K. Parker, 1/7/87: Study of Methoprene Residues In Representative Food Commodities Resulting From Exposure To Zoecon RF-209 Fogger, Zoecon Corporation, A Sandoz Company, Test No. 903-85, Unpublished.



ATTACHMENT A FORMULATOR'S EXEMPTION STATEMENT

EPA File Symbol or Product Reg	istration Number: 2724-
Applicant's Name and Address:	Zoecon Corporation, A Sandoz Company
19	12200 Denton Drive, Dallas, Texas 75234
product identified above, I he	
(1) Our product is an endingredient(s) (S)-Methoprene	d-use product, and it contains the active
the result of the incorporation of another product which contain	nt listed in paragraph (1) is present solely as n into the product (during formulation or packaging) ins that active ingredient, which is registered ch is purchased by us from another producer.
(3) Indicate by circling	the appropriate text which paragraph applies:
identified product is attached	fidential Statement of Formula for the above to this statement. That formula statement indicates, number, and product name, the source of the active aph (1).
a	R
file with the EPA is complete, requested on the current CSF for	1 Statement of Formula dated on current and accurate and contains the information orm No. 8570-4. The registered source(s) of the paragraph (1) is/are listed below.
Active Ingredient So	urce: Product Name and Registration No.
Applicant's authorized represen	ntative: Kelly (Signature)
	Kelly J. Parker
Dated: 9 June 1988	(Typed)



EPA File Symbol/Reg. No. 2724-	Date of application JUN 0 9 1988
Name of Product Zoecon RF-34	••••
Applicant's Name and Address Z	oecon Corporation
A	Sandoz Company
1	2200 Denton Drive
D	allas, Texas 75234
application. In addition, if ci is supported by all data in the or effects of this product or of substantially similar, and that required to be submitted if this of a product of identical or sim the data requirements in effect 2. I certify that, for each for registration that is an excluding written permission of the origin 3. I certify that, for each for registration that is not an I have obtained the written to cite that study; or I have notified in writing the cited to support this applicated to support this applicated the Federal Insecticide, Fun negotiations to determine where requirement of FIFRA and the any. The companies I have notified all active ingredients concited all option under Selective Independent of the Pay Statement be [X] Those companies who cited (Selective method)	he companies who have submitted data I have ation and have offered to: (a) Pay compensation with section 3(c)(1)(D) and 3(c)(2)(D) of gicide and Rodenticide Act; and (b) Commence ich data are subject to the compensation amount and terms of compensation due, if otified are: (Check one) on the Pesticide Data Submitters List for ontained in my product (Cite-all method or ective Method). (Also sign the General low.) have submitted the studies which I have
Date <u>IIIN 0 9 1988</u>	Signature Kelly J. Parker Title Regulatory Specialist
other persons, with regard t	by offer and agree to pay compensation to to the approval of this application, to the 3(c)(1)(D) and 3(c)(2)(D).
Date	Signature
	Title

350

SANDOZCR PROTECTION



Corporate Headquarters 1300 East Touhy Avenue Des Plaines, Illinois 60018 312.699.1616

January 15, 1988

Mr. Phillip Hutton
Product Manager 17
Registration Division (TS-767-C)
U.S. Environmental Protection Agency
Crystal Mall Building #2 Room 207
1921 Jefferson Davis Highway
Arlington, Virginia 22202

SUBJECT: Authorization To Access Data

<u>APEX</u> 5E, EPA Reg. No. 55947-88

<u>Methoprene Tech</u>, EPA Reg. no. 55947-90

<u>(S)-Methoprene Tech</u>, EPA Reg. No. 55947-109

Dear Mr. Hutton:

By copy of this letter Sandoz Crop Protection Corporation authorizes Zoecon Corporation, A Sandoz Company, to access any and all data submitted by Sandoz for registration of subject products to support registration of:

Zoecon RF-342 Emulsifiable Concentrate

If you have any questions regarding this authorization, please contact me directly at (312)390-3817.

Sincerely,

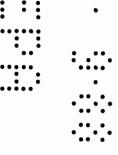
SANDOZ CROP PROTECTION CORPORATION

Ada M. Breaux

ldam. Breau

Manager, Biorational Registrations

mw





P. Hutton PM 17 RM 207

This is an accepted submission. One copy of the PPC diagnosis and one of the annotated bibliography are provided for your files. The PPC has already mailed out the submitter's copies of the two documents.

This is a partially accupted/rejected submission. A copy of the FPC diagnosis and of the annotated bibliography (if applicable) are provided for your files. A second copy is provided for your use in corresponding with the data submitter.

U. S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

ZOECON INDUSTRIES, INC. 12200 DENTON DRIVE DALLAS, TX 75234

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/09/88. Our staff has completed a preliminary analysis of the material. The results are provided as follows.

Your submittal was found to be substantially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exception(s) noted below. A copy of your bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents, and correct the noted exception(s) in future data submittals. If deficiencies were found which apply to your overall submission, they are described following this paragraph. If the deficiencies apply to specific studies, they are listed below following the applicable identification number or MRID. Thank you for your cooperation.

Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions.

If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

MRIDS 40653901 - 40653902 were all found to be deficient for the following reason/s:

Please include on each title page the guideline number(s) of the specific requirement(s) addressed by the study.

Zoecon Corporation

A SANDOZ Company 12005 Ford Road, Suite 800, Dallas, Texas 75234-7296, (214) 243-2321

TRANSMITAL DOCUMENT

PRODUCT NAME:

Zoecon RF-342 Emulsifiable Concentrate

TYPE OF SUBMISSION:

Application for New Registration

COMPANY:

Zoecon Corporation A Sandoz Company 12200 Denton Drive Dallas, Texas 75234

OFFICIAL:

Kelly J. Parker

Regulatory Specialist

SIGNATURE:

DATE:

June 9, 1988

MRID NUMBER:

DESCRIPTION:

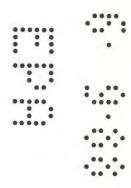
40653901

K. Parker, 6/9/88: Physical/Chemical Data-End-Use Product, Zoecon Corporation, A Sandoz

Company, Project T87-7, Unpublished.

40653902

K. Parker, 1/7/87: Study of Methoprene Residues In Representative Food Commodities Resulting From Exposure To Zoecon RF-209 Fogger, Zoecon Corporation, A Sandoz Company, Test No. 903-85, Unpublished.



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ON DIVISION DATA REVIEW RECORD Confidential Business Information - Does Not Contain National Security Information (E.O. 12055) 1. CHEMICAL NAME 2. IDENTIFYING NUMBER 3. ACTION CODE 4. ACCESSION NUMBER TO BE COMPLETED BY PM 5. RECORD NUMBER 6. REFERENCE NUMBER 7. DATE RECEIVED (EPA) 8. STATUTORY DUE DATE 9. PRODUCT MANAGER (PM) 10. PM TEAM NUMBER 14. CHECK IF APPLICABLE TO BE COMPLETED BY PCB 11. DATE SENT TO HED/TSS Minor Use Public Health/Quarentine 12. PRIORITY NUMBER Pert of IPM ☐ Substitute Chemical 13. PROJECTED RETURN DATE Sessonal Concern ☐ Review Requires Less Than 4 Hours 15. INSTRUCTIONS TO REVIEWER F. INSTRUCTIONS A. HED Total Assessment - 3(c)(5) C. BFSD Duration incremental Risk Assessment -3(c)(7) and/or E.L. Johnson memo of May 12, 1977. D. TSS/RD E. Other B. SPRD (Send Copy of Form to SPRD PM) Chemical Undergoing Active RPAR Review Chemical Undergoing Active Registration Standards Review 16. RELATED ACTIONS 17. 3(c)(1)(D) 18. REVIEWS SENT TO PL . DEF Use Any or All Available Information Use Only Attached Data Use Only the Attached Data for Formulation and Any or All Available Information on the Technical or Manufacturing Chemical. Use Only Attached Date O TB □ EEB RCB CH CH ☐ BFSD ☐ EFB NUMBER OF ACTIONS TYPE OF REVIEW MNR. USE Other Registration Petition EUP SLN Sec. 18 Inert TOXICOLOGY **ECOLOGICAL EFFECTS** RESIDUE CHEMISTRY ENVIRONMENTAL DATE CHEMISTRY OF JPK EFFICACY PRECAUTIONARY LABELING CONOMIC ANALYSIS 24. Include an Original and 4 (four) Representative 23. Date Returned to RD el Submitted onfidential Copies of This Completed Form Labels Showing (to be completed by Application Statement of HED) for Each Branch Checked for Accepted Uses Formula Attached Raview.

0-13 (Rev. 11-81) PREVIOUS EDITIONS ARE OBSOLETE.

Pages 357-360 -	*Confidential Statements of Formula may be entitled to confidential treatment*	